UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

LEACHCO, INC.'S POST-HEARING BRIEF

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LEACHCO, INC.'S POST-HEARING BRIEF

Respondent Leachco, Inc., pursuant to 16 C.F.R. 1025.46 and the September 16, 2022 Order on Prehearing Schedule (Dkt. No. 35), submits this Post-Hearing Brief.

* * *

The Commission's sole claim is that—despite Leachco's warnings—it is foreseeable that people will misuse the Podster and that the Podster's defective design creates a substantial risk of injury to the public. 15 U.S.C. § 2064(a)(2); *see Zen Magnets*, CPSC Dkt. 12-2, No. 163, 2017 WL 11672449, at *8 (CPSC Oct. 26, 2017) (Complaint Counsel bears the burden of proving by preponderance of the evidence that (1) a product is a defective product (2) that causes (3) a substantial risk of injury to the public). The Commission has not come close to proving its case.

First, the Commission failed to present reliable expert evidence that the Podster's design is defective. Instead, the Commission's expert witness Erin Mannen, Ph.D. used unproven methodologies, failed to identify safety/danger thresholds, and instead offered opinions based on *comparisons* between the Podster and, *e.g.*, a firm, flat mattress. Thus, for example, Dr. Mannen stated that that an infant in a Podster—under the assumption that the infant's face is enveloped by the Podster—will "rebreathe" *more* CO_2 than would an infant on a firm, flat mattress. But this "comparison" result fails to identify any threshold or standard to determine *at what point* rebreathing CO_2 becomes dangerous. Merely comparing test results is insufficient for expert testimony. *See, e.g.*, *Rovid v. Graco Children's Products Inc.*, No. 17-cv-01506-PJH, 2018 WL 5906075 (N.D. Cal. Nov. 9, 2018).

Dr. Mannen's other opinions rely on similar "comparison" results—even when part of the "baseline" control, such as a CAMI doll's "trunk" (*see* CCX-1, Mannen Report, pp. 19–20)—is "not realistic." Aug. 7, 2023 Tr. 117:16–118:1 (Mannen).

Indeed, Dr. Mannen did not validate any of her methods as correlating with actual human infants. In fact, one of the papers on which she expressly relies for methodology, warned that the test procedures "probably exaggerate the [rebreathing] effect an infant would experience." RX-28, p. 004. *See* Aug. 7, 2023 Tr. 136:4–22.

These problems are found throughout Dr. Mannen's testimony, which thus fails to support the Commission's claim that the Podster's design is defective.

Second, and similarly, the Commission failed to establish that foreseeable misuse is itself a defect, that it caused the three tragic deaths the Commission points to, or that it creates an unreasonable risk of injury to the public. Like Dr. Mannen, the Commission's "human factors" expert—long-time CPSC employee Celestine Kish—offers opinions without standards that are based almost entirely on anecdotal evidence. Thus, for example, Ms. Kish found on the internet what she described as an a "significant, alarming pattern" of consumer misuse; yet she never defines those terms or identified a standard to determine when a "pattern" becomes "significant" and "alarming." Aug. 8, 2023 Tr. 46:10–17. Similarly, Ms. Kish opines that "[m]any consumers are influenced by what they see other people do on social media," and "social media 'influencers' can have an outsized effect on consumer behavior" (CCX-2, Kish Report, p. 44 (¶86))—but Ms. Kish never provided a threshold or quantified how many consumers are so influenced, Aug. 8, 2023 Tr. 46:18–22.

Nor did Ms. Kish conduct any study to validate consumer internet use and internet influence. In a particularly egregious example, Ms. Kish claimed that "New York Magazine is a publication that most consumers would likely view as a credible, neutral reviewer of consumer products." CCX-2, p. 46 (¶90). But she admitted that she does not know how many consumers would view New York Magazine as a credible, neutral reviewer of consumer products; does not know the circulation of New York Magazine; does not know how many subscribers the magazine has; does not know the demographics of its readers; does not know if New York Magazine regularly reviews consumer products; and does not know if "most consumers" are even aware of New York Magazine. Aug. 8, 2023 Tr. 49:4–50:7. Thus, Ms. Kish's opinions are unsupported by valid, scientific methods and evidence.

As a result, Ms. Kish's testimony does not support the Commission's claim that foreseeable misuse is itself a defect, that it caused the three tragic deaths the Commission points to, or that it creates an unreasonable risk of injury to the public.[1]

Third, even if the Commission had established the Podster's design is defective, the Commission failed to prove that the three incidents were caused by any defect in the Podster. For one thing, the Commission did not call any witnesses with first-hand knowledge of the incidents themselves. Instead, the Commission offered its "In-Depth Investigation" (IDI) reports. These IDIs included both hearsay and non-hearsay

[1] As set forth in the Proposed Findings of Fact and Proposed Conclusions of Law, the Commission's pediatric-pulmonology expert, Dr. Umakanth Katwa, testified *generally* about infant physiology and breathing. *See* CCX-3 (Katwa Report), pp. 6–15. Because of the deficiencies in Dr. Mannen's and Ms. Kish's testimony, and the lack of evidence that the Podster is defective, Dr. Katwa's testimony is not relevant *to this case*. Dr. Katwa's testimony about the Podster's design and Leachco's marketing were stricken as beyond the scope of his expertise. *See* Aug. 2, 2023 Order (Dkt. No. 128), pp. pp. 6–7.

information and—more importantly—contain crucial factual discrepancies, such as the position in which infants were found (the Alabama and Virginia Incidents) and whether an infant was even in a Podster at all (the Texas Incident). These discrepancies undermine the Commission's claim that the Podster's design encourages dangerous movement and positioning. Without definitive proof of these allegations, the Commission cannot establish that *any* infant was found in a dangerous position and/or moved off the Podster into a dangerous situation.

Regardless, other evidence does show—overwhelmingly—that tragic accidents like the three incidents here arise because of human actions. The American Academy of Pediatrics reports that approximately 3,500 infant deaths each year are categorized as sudden infant death syndrome (SIDS). *See* RX-37, p. 001. The Commission's own reports further show that infant deaths tragically occur in all manner of infant products—including many products (like cribs) that the Commission itself *promotes* for safe sleep. *See* RX-20 (CPSC Reports, *Injuries and Deaths Associated with Nursery Products Among Children Younger than Age Five* (2009–22)). These CPSC reports further show that most of these deaths occur—even in CPSC-approved cribs and bassinets—because of unsafe-sleep environments. *See id.*, pp. 152–53. The Commission's expert witnesses, Ms. Kish and Dr. Umakanth Katwa, acknowledged these facts. *See* Aug. 8, 2023 Tr. 91:21 (Kish); Aug. 9, 2023 Tr. 14:6−15, 47:6–8 (Katwa).

Fourth, as a result of these (from the Commission's point of view) factual complications, the Commission attempts to apply a standard—perfect parental supervision—to justify its claim that the Podster's *design* leads to, *e.g.*, bedsharing or other

unsafe-sleep practices. *See* CCX-2 (Kish Report), p. 5 (opining that the Podster "presents a hazard that cannot be mitigated by warnings and depends on perfect parental supervision, which is not possible"). But this standard is found nowhere outside of this case. Indeed, the Commission *itself* doesn't apply this standard—as Ms. Kish admitted on the witness stand. The Commission—like the American Academy of Pediatrics and the National Institutes of Health—recognizes that young infants can and do fall asleep just about anywhere, and it recommends moving sleeping infants to safe-sleep environments. The Commission's attempt to hold Leachco to a standard (of *perfection*) that the Commission itself doesn't follow is, to say no more, arbitrary and irrational.

Fifth, even if the Commission had proven—though it has utterly failed to do so—that the Podster's design defect (if any) caused the three tragic deaths at issue and that it creates a risk that infants could roll into dangerous positions, the Commission still cannot show that this alleged defect created a substantial risk of injury to the public. Leachco has sold approximately 180,000 Podsters. The Commission has evidence of no more than three injuries remotely associated with the Podster. Assuming each Podster is used only a single time, the chances of death or injury would be 0.0017% (3 / 180,000)—less than two-one-thousandths of a percent. Ms. Kish testified that it's "likely" that each Podster is used multiple times. Assuming each Podster is used only ten times, the rate of injury or death would be the injury rate (3 / 1,800,000) would be 0.0000017, or 0.00017 percent. The "risk" thus approaches zero.

* * *

Leachco, of course, sees all infant deaths as tragic—particularly since Leachco is in the business of helping young families. But Leachco should not be held out as a scapegoat for unfortunate accidents that can and do arise in all manner of products and situations. The Commission should never have brought this baseless case. And the Court should dismiss it.

PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

LEACHCO'S PROPOSED FINDINGS OF FACT

1. Respondent Leachco is an Oklahoma corporation founded in 1988 by Jamie Leach and Clyde Leach in Ada, Oklahoma.[2]

2. Leachco currently employs approximately 30 people and manufactures, distributes, and offers for sale more than 90 products for infants, children, and adults.[3]

3. Jamie Leach designs Leachco's products including the Podster.[4]

4. The Consumer Product Safety Commission is a federal executive agency of the United States.

The Podster

5. The Podster is an infant lounger designed in 2008 by Leachco.[5]

6. Leachco first offered the Podster for sale in 2009.[6]

7. Leachco has sold approximately 180,000 Podsters.[7]

8. It is likely that each Podster is used many times.[8]

9. The Podster is designed and marketed as an infant lounger.[9]

10. The Podster is not and has never been advertised by Leachco as a sleep product.[10]

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[2] JX-51, Joint Stipulations, ¶¶1, 8.
[3] JX-51, Joint Stipulations, ¶¶2, 8.
[4] JX-51, Joint Stipulations, ¶6.
[5] Aug. 8, 2023 Tr. 112:2–3.
[6] JX-51, Joint Stipulations, ¶12.
[7] JX-51, Joint Stipulations, ¶13.
[8] Aug. 8, 2023 Tr. 68:9–11 (Kish).
[9] JX-51, Joint Stipulations, ¶9.
[10] JX-51, Joint Stipulations, ¶18.

11. The Podster contains warnings that the product should not be used for sleep and that adult supervision is always required.[11]

12. The Podster contains warnings that the product should be used only on the floor, and not in another product, such as a crib, on a bed, table, playpen, counter, or any elevated surface.[12]

13. The Podster contains warnings that infants should not be placed prone or on their side in the product.[13]

14. The Podster contains instructions that it should be used for infants not to exceed 16 pounds and should not be used if an infant can roll over.[14]

15. The Podster contains warnings and instructions that use of the product in contravention to these warnings could result in serious injury or death.[15]

16. The Podster is not a banned inclined infant sleep product under 15 U.S.C. § 2057d.[16]

17. The Podster is not a banned infant pillow under 16 C.F.R. § 1500.18(a)(16).[17]

Incidents Allegedly Associated with the Podster

18. Complaint Counsel claims three incidents were associated with the Podster: the "Alabama Incident," the "Texas Incident," and the "Virginia Incident."

[11] JX-51, Joint Stipulations, ¶19.
[12] JX-51, Joint Stipulations, ¶20.
[13] JX-51, Joint Stipulations, ¶21.
[14] JX-51, Joint Stipulations, ¶22.
[15] JX-51, Joint Stipulations, ¶23.
[16] Tr. 36:1–9 (Kish).
[17] Tr. 35:6–21; 36:7–9 (Kish).

19. Since 2009, there have been no other reported injuries or deaths associated with the Podster.

20. Complaint Counsel did not offer any first-hand accounts of the Alabama, Texas, or Virginia incidents. Instead, the Commission relied exclusively on In-Depth Investigation Reports (IDIs) prepared by CPSC personnel.[18]

21. IDIs generally include narrative summaries written by CPSC personnel, copies of police and/or fire-department and/or EMS reports, photographs purportedly taken of the incident scenes, and medical-examiner/autopsy reports.[19]

22. As detailed below, the IDIs contain materially conflicting information.[20] Further, as discussed in the Conclusions of Law section, below, the IDIs contain both hearsay and non-hearsay (or exceptions to hearsay) information. The Court admitted the IDIs into evidence, stating that they were "generally admissible."[21] The Court noted, however, that they were admissible "to the extent that they are comprised of reliable hearsay, they could be argued to be admissible subject to the objections that you have raised to that type of evidence[;] [a]nd to the extent that they are not hearsay in the sense that these were documents that prompted some action by the

[18] Aug. 7, 2023 Tr. 173:6–175:7 (testimony of E. Philips, CPSC investigator); Alabama IDI: JX-06 (redacted) & JX-07 (unredacted); Texas IDI: JX-08 (redacted) & JX-09 (unredacted); Virginia IDI: JX-10 (redacted), JX-11 (unredacted), JX-12A(1) (redacted MECAPS report), & JX-12B(1) (unredacted MECAPS report). *See also* Aug. 8, 2023 Tr. 74:14–19 (Ms. Kish's stating that a CPSC investigator prepared the narrative in the Alabama IDI).

[19] *See* JX-06, JX-07, JX-08, JX-09, JX-10, JX-11, JX-12A(1), & JX-12B(1).

[20] *See* Aug. 8, 2023 Tr. 70:20–22 (Ms. Kish's acknowledging that IDIs have conflicting information); Aug. 9, 2023 Tr. 22:15–17 (Dr. Katwa's admitting inconsistent information in the Alabama Incident IDI).

[21] Aug. 7, 2023 Tr. 203:15–16.

investigators and are not offered for the truth contained in those documents, they would be admissible on that basis as well."[22]

Alabama Incident

23. According to the report from the Jefferson County Medical Examiner's Office,[23] a four-month-old boy was brought to a daycare on the morning of December 16, 2015.[24]

24. According to the Medical Examiner, daycare personnel had placed him in an oval-shaped cushion—apparently a Podster—which was placed in a crib.[25] A bottle was placed in the boy's mouth, and he was left unattended.[26] He was later found unresponsive and making a gurgling sound.[27]

25. According to the Medical Examiner, the boy had developed bronchiolitis at two months of age and was being treated at home with Albuterol; though he apparently had no symptoms requiring use of Albuterol for at least two days before this incident.[28]

26. There are conflicting statements in the autopsy report concerning which position the infant was found in; one report said he was found "essentially face down," while another report said he was found lying "in a bed on his back."[29]

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[22] Aug. 8, 2023 Tr. 9: 3–11.
[23] JX-06, pp. 14–25; JX-07, pp. 13–24.
[24] JX-06, p. 25.
[25] JX-06, pp. 19, 20, 25.
[26] JX-06, p. 25.
[27] JX-06, p. 25.
[28] JX-06, pp. 19, 25.
[29] JX-06, pp. 19, 25; *see also* Aug. 8, 2023 Tr. 74:20–76:20 (Kish).

27. The infant was taken to Children's Hospital of Birmingham where cardio-pulmonary resuscitation was performed.[30] Tragically, his condition did not improve, and he passed away approximately six days after medical support was withdrawn.[31]

28. The autopsy report did not reveal an obvious cause of death.[32] It was noted that the infant's death was "consistent with" an "asphyxia type" death.[33] Ultimately, according to the Medical Examiner's office, the cause of death was "best listed as complications of asphyxia with the manner of death being accident."[34]

Texas Incident

29. The only documents that purport to describe the facts of the Texas Incident are hearsay.

30. According to the CPSC's narrative in the IDI, a 17-day-old girl was found unresponsive in her parents' adult bed.[35]

31. According to a police report in the IDI, the victim's mother, who was "hysterically crying uncontrollably," told police that the victim was last awake at 2:00 a.m. for feeding, after which the mother placed the victim in her "nursing pillow"

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[30] JX-06, p. 19.
[31] JX-06, p. 19.
[32] JX-06, p. 19.
[33] JX-06, p. 19.
[34] JX-06, p. 19. Complaint Counsel's proffered expert Dr. Katwa attempted to resolve a factual discrepancy in the Alabama Incident, even though he did not witness anything. Aug. 9, 2023 Tr. 17:1–9; 18:2–19:2. As noted above, the IDI concerning the Alabama Incident includes information that the infant was found on his back and face up. Dr. Katwa noted this discrepancy but, in his report, stated that the infant was found face down. Aug. 9, 2023 Tr. 17:10–16; 18:2–19:2. This Court previously ruled that "[until such time as a foundation is established for use or admission of the IDIs at hearing," the factual assertions of Complaint Counsel's experts "about the incidents are excluded." Aug. 2, 2023 Order (Dkt. No. 128), p. 8. As explained elsewhere, Complaint Counsel failed to provide foundation to explain the factual discrepancies in the IDIs. *See below*, Proposed Conclusions of Law ¶¶290–295. Experts may, of course, provide an opinion only as to facts already in the record, but they cannot be vehicles for introducing additional facts or resolving factual inconsistencies. *See* Aug. 2, 2023 Order (Dkt. No. 128), pp. 7–8.
[35] JX-08, p. 8.

between the mother and father, and the mother fell asleep.[36] The police report also states that the victim's mother woke up around 5:45 a.m., realized the victim was not in her nursing pillow, and yelled to the father to wake him up to see where the infant was.[37] The mother saw the father raise the bed sheet and observed the victim lying on her back, cold to the touch and unresponsive.[38]

32. According to a follow-up interview by the police, both parents said that the baby slept with them on her "pink pillow" between them.[39] The mother said she "fed the victim at 2 am and went back to sleep."[40] Here, the mother did not say that, after feeding the victim, the mother placed the victim back in the pillow. The mother also said that she "woke up around 6 am to get a drink and she asked her husband, where's the victim. She [the mother] then observed the victim lying beside the pink baby pillow in the bed."[41] The parents called 911 and started CPR.[42]

33. According to the CPSC's narrative, the infant's mother "reported that she fed the victim approximately 3 ounces of breast milk at 0200 hours before placing the

[36] JX-08, p. 33.
[37] JX-08, p. 33.
[38] JX-08, p. 33.
[39] JX-08, p. 34.
[40] JX-08, p. 34.
[41] JX-08, p. 34. Complaint Counsel's proffered expert Dr. Katwa testified that the "infant somehow managed to slide down and fell off the Podster." Aug. 9, 2023 Tr. 19:22–20:18. Complaint Counsel's proffered expert witness Ms. Kish similarly testified that "the victim had fallen off the Podster." Aug. 8, 2023 Tr. 70:11–14. *See also* JX-1 (Mannen Report) p. 60 (speculating that the infant "apparently rolled off the pillow"). Again, none of the expert witnesses witnessed the incidents. *See* Aug. 9, 2023 Tr. 20:19–22:1 (Katwa); Aug. 8, 2023 Tr. 70:15–19 (Kish). As noted below, Proposed Conclusions of Law ¶¶290–295, because Complaint Counsel failed to offer first-hand evidence concerning the incidents, Complaint Counsel cannot use expert witnesses (who, of course, were not themselves first-hand witnesses) to resolve factual disputes.
[42] JX-08, p. 34.

victim to sleep. The victim was placed face up on a nursery pillow lounger which was present on top of a queen size bed."[43]

34. It appears that the infant's lower body was covered with a blanket.[44]

35. The medical-examiner's report does not mention an adult bed but does state that "[p]ositional asphyxia due to co-sleeping in an unsafe sleep environment cannot be excluded as contributory given the circumstances at the time of death and the finding of anterior lividity at the time of autopsy."[45]

36. Apparently, the infant had been making gasping sounds sometimes and was scheduled for a doctor's appointment two days after she passed away.[46]

37. The Medical Examiner concluded that the cause and manner of death were "undetermined."[47] The Medical Examiner therefore classified the cause of death as sudden unexpected death in infancy (SUDI), which applies after a "thorough investigation, medical history review, autopsy, and appropriate laboratory testing fail to identify a specific cause of death."[48] The Medical Examiner noted that positional asphyxia due to "co-sleeping in an unsafe sleep environment" could not be excluded "as contributory."[49] Ultimately, the manner of death was certified as "undetermined."[50]

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[43] JX-08, p. 4.
[44] JX-08, p. 19.
[45] JX-08, p. 13.
[46] JX-08, pp. 4, 22.
[47] JX-08, p. 13.
[48] JX-08, p. 13.
[49] JX-08, p. 13.
[50] JX-08, p. 13.

38. Pictures purportedly from the scene show several infant products, including a baby bouncer and three different infant loungers.[51] There also appears to be an empty bottle of beer in the trash can.[52]

39. Dr. Katwa and Ms. Kish acknowledged the possibility that the mother fed the baby and fell asleep without placing the baby in the Podster.[53] Dr. Katwa and Ms. Kish further acknowledged the connection between breastfeeding and mothers' sleeping.[54] Indeed, Ms. Kish's report relies on a study that confirms this connection: Drago 2021.[55] According to this study, "the 2016 AAP Safe Sleep Guidelines acknowledged the link between bed sharing and breastfeeding, and that parents may fall asleep while breastfeeding." Ms. Kish agreed with this statement.[56]

Virginia Incident

40. In the Virginia Incident, a three-month-old infant passed away on October 25, 2021 at a home-based daycare run by a husband and wife.[57] According to a sheriff's report, the infant was dropped off at the daycare by her mother.[58] Later, the infant was placed in a Podster for a nap.[59] She was placed on her back and propped

[51] JX-08, pp. 45, 48.
[52] JX-08, p. 48.
[53] Aug. 9, 2023 Tr. 23:7–13 (Katwa); Aug. 8, 2023 Tr. 71:1–6 (Kish).
[54] Aug. 9, 2023 Tr. 23:14–17 (Katwa); Aug. 8, 2023 Tr. 65:18–66:3 (Kish).
[55] Drago, et al., "Infant fatality patterns in shared sleep: keys to intervention strategies?" *Proceedings of the 2021 HFES 65th International Annual Meeting*, 1322-1326, at 1323-25 (2021). *See* CCX-2 (Kish Report), p. 63 n.114 (citing Drago 2021).
[56] Aug. 8, 2023 Tr. 64:18–66:3.
[57] JX-10, pp. 5–6.
[58] JX-10, p. 6.
[59] JX-10, pp. 6, 11.

up because she had "so much congestion."[60] The Podster was placed in a play yard or playpen; a nursing blanket was also present.[61]

41. Approximately 45 minutes later, the husband noticed the infant had turned over slightly, but still primarily lying on her back.[62] He said that the infant's cheek was slightly against the side of the lounger but that her nose and mouth were not touching the lounger.[63] When he approached to move her, he noticed that her body was limp. He screamed, took her to a couch, and performed CPR.[64] 911 was called.[65]

42. The infant was taken to a hospital, where she was tragically pronounced dead.[66]

43. The autopsy report notes that the Virginia infant had chronic bronchitis.[67] A week before she passed away, she was taken to a doctor for congestion.[68] The infant also had a possible ear infection.[69] The infant was taking Albuterol.[70]

44. The infant had been sick for several days.[71]

45. A week before the incident, the infant had been taken to the pediatrician because she was "very congested;" she was prescribed respiratory treatments for breathing/wheezing.[72]

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[60] JX-10, p. 11.
[61] Ex. JX-10, pp. 6, 11.
[62] Ex. JX-10, p. 51.
[63] Ex. JX-10, p. 51.
[64] JX-10, p. 11.
[65] Ex. JX-10, p. 11.
[66] Ex. JX-10, p. 11.
[67] Ex. JX-12A(1), p. 5.
[68] Ex. JX-12A(1), p. 9.
[69] Ex. JX-12A(1), p. 8.
[70] Ex. JX-12A(1), p. 8.
[71] Ex. JX-10, p. 11.
[72] Ex. JX-10, p. 6.

46. Two days before the incident, the infant's mother called 911 because the infant was having trouble breathing.[73] The infant was "very congested" and had vomited mucus and had a "difficult time" breathing.[74]

47. According to the autopsy report for the Virginia Incident, the cause of death was "[s]udden unexpected infant death with unsafe bedding and positioning," and the manner of death was "[u]ndetermined."[75]

48. According to the IDI, a doll reenactment purports to show the face of the doll against the side of the Podster,[76] but as the CPSC's Ms. Kish testified, "it is not known whether the victim's face was actually in this position."[77] Ms. Kish admitted that no evidence shows whether the infant's face was in the position that the doll reenactment purported to show.[78]

The Commission's Allegations of Design Defect

49. The Commission claims that the Podster's inclined, compliant, soft, and insufficiently permeable design creates an alleged risk. The Commission alleges that the Podster is defective because of airflow obstruction, lack of firmness, facilitation of movement on and off the product, facilitation of rolling, positional asphyxia, and encouragement of bedsharing.[79]

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[73] Ex. JX-10, p. 11.
[74] Ex. JX-10, p. 11.
[75] Ex. JX-12A(1), pp. 3, 5.
[76] JX-10, p. 35.
[77] CCX-2 (Kish Report) pp. 72–73. *See also* Aug. 8, 2023 Tr. 71:7–18.
[78] Aug. 8, 2023 Tr. 71:19–22. Again, Complaint Counsel's proffered witness Dr. Katwa attempted to construe facts favorable to the CPSC's arguments, even though he admittedly did not witness the incident. Here, Dr. Katwa testified that the baby's "[f]ace and neck were turned to the right and nose touching the lounger," but he admitted he did not witness the incident and was unaware of a contrary description elsewhere in the Virginia IDI. Aug. 9, 2023 Tr. 23:21–25:1.
[79] *See* Compl. ¶¶48–52.

50. The Commission does not allege that a reasonable alternative design exists.

51. To support this claim, the Commission proffered expert testimony from Erin M. Mannen, Ph.D.; Celestine Kish; and Umakanth Katwa, M.B.B.S., M.D.[80]

52. Dr. Mannen, who has Ph.D. in Mechanical Engineering from the University of Kansas, was retained by Complaint Counsel "to evaluate Podster products manufactured by Leachco, Inc., and assess whether their design creates a risk of injury for infants."[81]

53. Dr. Mannen opines that the design of the Podster:

a. Causes a flexed head/neck and flexed trunk posture during supine lying, inhibiting normal breathing;

b. Facilitates some types of rolling on or off of the product, introducing concerning suffocation-related risks for the infant;

c. Increases abdominal fatigue if an infant finds themselves prone in the pillow, increasing the risk of suffocation;

d. Negatively affects the ability of an infant to self-rescue from the prone position to a safe breathing position;

e. Permits an infant in a supine position to move its face into the sides of the Podster where its nose and mouth are obstructed; and

f. Negatively affects the ability of an infant to breathe normally if they are prone or side-facing in the product.[82]

[80] The Court will discuss the substance of the CPSC's proffered expert testimony below in the [Proposed] Conclusions of Law.
[81] CCX-1, p. 5.
[82] CCX-1, pp. 5–6.

54. Celestine Kish, a 34-year employee of the CPSC,[83] opines that consumers' observations of other consumers' misuse can encourage misuse and that it is foreseeable that consumers will use the Podster in a dangerous manner.[84]

55. Dr. Katwa testified about the general physiology of infant breathing.[85]

Safe-Sleep Environments

56. Government agencies and children's organizations recommend safe-sleep environments.[86] These recommendations include: placing young infants on their backs for sleep; use a firm, flat mattress without extra bedding or blankets; breastfeeding; sleeping in the parents' room (but not the parents' bed).[87]

57. These recommendations recognize that young infants (and parents) may fall asleep in environments that don't meet these recommendations. Accordingly, the recommendations include actions to take when this happen:

a. The CPSC recommends: "Transfer the baby to a firm, flat crib, bassinet, play yard or bedside sleeper if they fall asleep in a swing, bouncer, lounger, or similar product."[88]

b. "Car seats, strollers, and sitting devices are not recommended as baby's regular sleep or nap space. If baby falls asleep in a sitting

[83] *See* CCX-2 (Kish Report). The Court previously ordered that Ms. Kish's testimony concerning alleged defects in Leachco's warnings was stricken and admitted Ms. Kish's report into evidence on that basis. Aug. 2, 2023 Order (Dkt. No. 128), pp. 3–5. Accordingly, the Court does not consider Ms. Kish's opinion that the Podster's warning system fails to protect infants from hazards (CCX-2, pp. 7–31).
[84] CCX-2, pp. 1–2.
[85] *See* CCX-3 (Katwa Report). As previously ordered, Dr. Katwa is not qualified to testify about the Podster's design, alleged use of the Podster, and alleged defective marketing by Leachco. Aug. 2, 2023 Order (Dkt. No. 128), pp. 6–7. Accordingly, his opinions concerning the Podster's design, alleged defects in the Podster, alleged use of the Podster, and marketing were stricken. *Id*.
[86] *See* RX-02 (CPSC announcement); RX-3 (NIH Statement); RX-37 (AAP Policy Statement, Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment).
[87] *See, e.g.*, RX-37, p. 007–011.
[88] RX-02, p. 004.

or carrying device, move them to their regular sleep space as soon as possible."[89]

c. "If you fall asleep while feeding or comforting baby in your bed, put them back into their own sleep area, like a bassinet, next to your bed as soon as you wake up."[90]

d. "You should also think about how tired you are before you bring baby into your bed to feed or comfort. If there's a chance you may fall asleep, remove all items and bedding from your side of the bed before adding baby to the bed. Removing pillows, blankets, and unfitted sheets from the area reduces the risk of suffocation and strangulation for baby."[91]

e. "Sitting devices, such as car seats, strollers, swings, infant carriers, and infant slings, are not recommended for routine sleep in the hospital or at home, particularly for infants aged <4 months. When infants fall asleep in a sitting device, remove them from the product and move them to a crib or other appropriate flat surface as soon as is safe and practical. Car seats and similar products are not stable on a crib mattress or other elevated surfaces."[92]

58. Despite these recommendations, approximately 3,500 infant deaths a year are classified as SIDS—Sudden Infant Death Syndrome.[93]

59. These deaths occur in cribs, adult beds, car seats, infant-bouncer seats, and all manner of sleep environments.[94]

60. The risk that the Commission alleges, of course, does not exist in a vacuum. Risk must be balanced against a Product's utility.

[89] RX-03, p. 003.
[90] RX-03, p. 006.
[91] RX-03, p. 007.
[92] RX-37, p. 010 (footnote citations omitted).
[93] Aug. 9, 2023 Tr. 47:6–8.
[94] RX-37, p. 001; Aug. 9, 2023 Tr. 47:6–8 (Katwa).

61. Leachco's expert witness, Peggy Shibata, upon cross-examination by Complaint Counsel, testified that the Podster could be used while caregivers prepare a meal, pay bills, check email, and give a hand to the infant's siblings.[95]

62. Ms. Shibata also testified that the risk here is caused, not by the Podster's design, but by failure to follow safe-sleep recommendations.[96]

[redacted]

[95] Aug. 10, 2023 Tr. 33:8–35:16; 36:5–16.
[96] RX-1 (Shibata Report), pp. 9–10.
[97] [redacted]
[98] [redacted]

LEACHCO'S PROPOSED CONCLUSIONS OF LAW

I. CONSUMER PRODUCT SAFETY ACT

COMPLAINT COUNSEL'S BURDEN OF PROOF

1. Under the Consumer Product Safety Act, the Commission may order a manufacturer to take remedial action if it proves that a consumer product presents a "substantial product hazard." 15 U.S.C. § 2064(a), (c)-(d).

2. "Complaint Counsel shall have the burden of sustaining the allegations of any complaint." 16 C.F.R. § 1025.43(b)(1).

3. Complaint Counsel must meet prove by the preponderance of the evidence that (1) the Podster is a defective product (2) that causes (3) a substantial risk of injury to the public. *See Zen Magnets*, CPSC Dkt. 12-2, No. 163, 2017 WL 11672449, at *8 (CPSC Oct. 26, 2017).

4. The preponderance of the evidence standard "is not a mere weighing of the amount of testimony, number of witnesses, and the like," but requires "the consideration of the credibility and qualifications of witnesses and the significance of particular testimony in making the overall determination of whether the total evidence for a fact being true is more convincing than the evidence for the fact being not true." *In the Matter of Dye and Dye*, CPSC Dkt. 88-1, 1989 WL 435534, *4 (CPSC July 17, 1991).

II. COMPLAINT COUNSEL FAILED TO CARRY ITS BURDEN

A. Complaint Counsel failed to prove that the Podster is defective

1. Allegations and proffered evidence

5. The Commission alleges a design defect. *See* Compl. ¶¶ 48–52.

6. The Commission claims that the Podster's design is defective because it obstructs airflow and lacks firmness and thereby creates a risk of suffocation and/or "rebreathing"; facilitates movement on and off the Podster; allows rolling; causes increased flexion that inhibits breathing; enables infants to slide into a "slouched" position, further inhibiting breathing; causes muscle fatigue that reduces an infants' ability to self-rescue if an infant is in a dangerous position; and leads to unsafe bed-sharing.

7. To support its claim, Complaint Counsel proffered expert testimony from (a) Erin M. Mannen, Ph.D., an expert in biomechanical engineering expert; (b) Celestine Kish, a long-time CPSC employee, who offered testimony about foreseeable use of the Podster; and (c) Umakanth Katwa, M.D., an expert in pediatric pulmonology. *See* CCX-1 (Mannen Report); CCX-2 (Kish Report); CCX-3 (Katwa Report).

2. "Product defect"

8. The Act defines a "substantial product hazard" as "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." *Id.* § 2064(a)(2).

9. The term "product defect" is not defined by the act, and thus the Court looks to the Commission's regulation (16 C.F.R. § 1115.4); the common law; and the "'common practice of consulting dictionary definitions to clarify their ordinary meaning.'" *United States v. TRW Rifle 7.62X51mm Caliber, One Model 14 Serial 593006*, 447 F.3d 686, 689 (9th Cir. 2006) (quoting *United States v. Carter*, 421 F.3d 909, 911 (9th Cir. 2005)).

10. According to the Commission's regulations, a design defect may be present "if the design presents a risk of injury to the public" or "if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended." 16 C.F.R. § 1115.4.[99] A "risk of injury" includes "a risk of death, personal injury, or serious or frequent illness." 15 U.S.C. § 2052(a)(14).

11. According to the common law and dictionary definitions, a "product defect" means "[a]n imperfection in a product that has a manufacturing defect or design defect or is faulty because of inadequate instructions or warnings." *See* "manufacturing defect; design defect; marketing defect." Product Defect (1967), *Black's Law Dictionary* (11th ed. 2019); *see also* Restatement (Third) of Torts § 2 (Am. L. Inst. 1998). And a product is "defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe." Third Restatement § 2(b).

12. The Commission also claims that the Podster is defectively designed because it is foreseeable—despite Leachco's warnings against sleep, bedsharing, unsupervised use, etc.—that consumers will misuse the Podster. The Court rejects this *definition* of "defect." The Commission's regulation says that the Commission may *consider*, among other things, the "role of consumer misuse and the foreseeability of

[99] Leachco has objected that 16 C.F.R. §§ 1115.4, 1115.12, and related regulations are merely interpretative—and, therefore, non-binding—regulations. Leachco's objection is preserved. Leachco also raised constitutional objections, and those objections are preserved as well.

such misuse." 16 C.F.R. § 1115.4. The Court therefore *considers* foreseeable misuse, but it does not equate foreseeable misuse with "defect." *See* July 6, 2023 Order (Dkt. 99), p. 4 ("Reasonably foreseeable misuse is a factor on which Complaint Counsel may base its defective product claim against the Podster.") (citation omitted).

13. Complaint Counsel has not demonstrated that the Podster is "unreasonably dangerous for its intended use." *Hunter v. Shanghai Huangzhou Elec. Appliance Mfg. Co.*, 505 F. Supp. 3d 137, 152–53 (N.D.N.Y. 2020).

14. The testimony of Complaint Counsel's expert, Dr. Mannen, failed to establish that the risk of injury from the Podster outweighs its utility or that an alternative design could reduce or avoid the injuries alleged to be caused by the Podster. *See Zen Magnets*, 2017 WL 11672449, *29–32; 16 C.F.R. 1115.4(e). *See below*, Proposed Conclusions of Law ¶¶24–175.

15. The testimony of Complaint Counsel's expert, Ms. Kish, failed to establish that it is reasonably foreseeable that an objective consumer would disregard the Podster's warnings and instructions and misuse the Podster. *See below*, Proposed Conclusions of Law ¶190–236.

16. And because the testimony of Dr. Mannen and Ms. Kish do not show the Podster contains a product defect, the Court concludes that the testimony of Dr. Katwa does not help the trier of fact here. *See below*, Proposed Conclusions of Law ¶¶176–189.

3. The Commission's proffered expert testimony failed to establish a product defect

Daubert standard

17. The Federal Rules of Evidence apply here. *See* 16 C.F.R. § 1025.43(a) ("Unless otherwise provided by statute or these rules, the Federal Rules of Evidence shall apply to all proceedings held pursuant to these rules.").

18. Because of the unique nature of this testimony, courts must ensure the testimony's reliability and relevance. Judges thus have a "gatekeeping" function to ensure that a proposed expert's testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). Judges must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

19. Rule 702 of the Federal Rules of Evidence requires that a proffered witness be "qualified as an expert by knowledge, skill, experience, training, or education." Even if a witness is qualified, her opinion may be admitted only if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Id.

20. The proffered expert witness must be qualified, the testimony must help the trier of fact, and the testimony must be reliable.

21. Accordingly, a *qualified* expert's testimony will be admitted only if the testimony is (1) reliable and (2) relevant. Fed. R. Evid. 702; *Daubert*, 509 U.S. at 592–93. Therefore, the Court must determine *first* whether Dr. Katwa's reflects "scientific knowledge," *i.e.*, whether the findings are "derived by the scientific method," and whether the work product is "good science," or, put another way, reliable and trustworthy. *Daubert*, 509 U.S. at 590, 590 n.9, 593. The court determines *second* whether the testimony is "relevant to the task at hand." *Id*. at 597.

22. The proponent of an expert witness bears the burden by a preponderance of the evidence that a witness's testimony meets the standards of Rule 702. *See Daubert*, 509 U.S. at 592 n.10*; Sardis v. Overhead Door Corp.*, 10 F.4th 268, 283–84 (4th Cir. 2021); *Krik v. Exxon Mobil Corp.*, 870 F.3d 669, 673 (7th Cir. 2017); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999).

4. Dr. Mannen's testimony failed to establish a product defect

a. Dr. Mannen is qualified to testify only on biomechanical engineering topics

23. Dr. Mannen has Ph.D. in Mechanical Engineering from the University of Kansas, has researched biomechanics for 14 years, and specialized in infant biomechanics for eight years.[100]

24. After receiving her Ph.D., Dr. Mannen was an adjunct professor in the Department of Biomedical Engineering, School of Engineering, at the University of

[100] CCX-1 (Mannen Report), p. 5; *id*. Ex. A.

Arkansas.[101] Currently, Dr. Mannen is an assistant professor in the Mechanical and Biomedical Engineering Department at Boise State University.[102]

25. Dr. Mannen has published articles in the biomechanics engineering area.[103]

26. Dr. Mannen is not a doctor or nurse, has no medical or nursing degree, and has no certifications in medicine.[104]

27. The Court concludes that Dr. Mannen is qualified to offer expert testimony on biomechanical engineering. But she is not qualified to testify on medical questions.

b. Dr. Mannen's methodologies are not reliable

28. Dr. Mannen ran various tests—described below—on ten Podsters, five standard (similar to JX-01) and five "plush" Podsters (similar to JX-02).

29. Dr. Mannen relies heavily on methodologies and results from three studies she directed on behalf of the CPSC: (1) Biomechanical Analysis of Inclined Sleep Products (Mannen 2019); (2) Pillows Product Characterization and Testing Study (Mannen 2022); and (3) Crib Bumper Product Characterization and Testing (Mannen 2023)—particularly Mannen 2019 and Mannen 2022.[105]

30. None of these studies has been peer-reviewed.[106]

31. And none of the testing methods Dr. Mannen used have been validated to show that these test results accurately correlate to results for live infants.

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[101] CCX-1, Ex. A.
[102] CCX-1, Ex. A.
[103] CCX-1, Ex. A.
[104] Aug. 7, 2023 Tr. 168:2–12.
[105] *See* CCX-1, pp. 8-12 (discussion); 13–14, 16, 21, 23, 25, 29, 32-33, 34, 38, 44, 46, 48–49 (cites).
[106] Aug. 7, 2023 Tr. 83:22–85:4.

Dr. Mannen's Methodologies

Trunk Flexion

32. Dr. Mannen opined that the Podster's design causes a flexed neck and flexed trunk posture during supine lying, which inhibits normal breathing.[107]

33. To measure trunk flexion, Dr. Mannen used two four-plane sagittal devices, one that purported to mimic a newborn and the other to mimic an infant.[108]

34. A picture of this device is from CCX-1, p. 17:

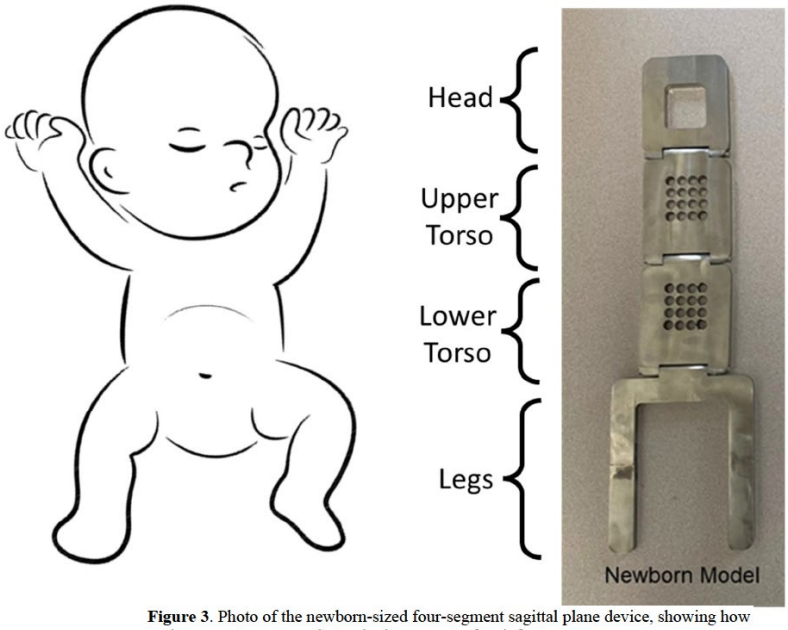

Figure 3. Photo of the newborn-sized four-segment sagittal plane device, showing how each segment corresponds to a body segment of an infant.

35. Dr. Mannen placed a newborn-sized and an infant-sized device in ten Podsters three times each, in two different positions—"intended" placement and "slouched," as shown in this picture, from CCX-1, p. 18:

[107] CCX-1, p. 6; *see also* Aug. 7, 2023 Tr. 111:2–8.
[108] CCX-1, pp. 16–18.

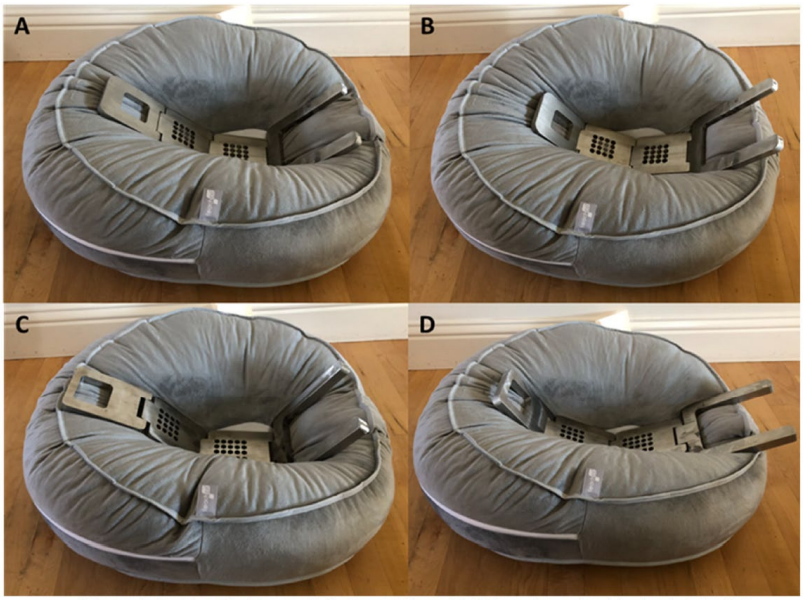

Figure 4. Leachco Podster sagittal plane testing with (A) newborn-sized device in intended placement, (B) newborn-sized device in slouched placement, (C) infant-sized device in intended position, and (D) infant-sized device in slouched position.

36. Dr. Mannen then measured the angle of the device's "trunk" compared to the angle on a firm, flat mattress.[109] That is, Dr. Mannen measured "the increase in trunk flexion angle compared to the flat crib mattress condition."[110]

37. According to her measurements, during "intended" placement, the "trunk" of the newborn-size sagittal device was flexed on average 32° compared to a flat mattress, and the "trunk" of an infant-size device flexed on average 36° compared to a flat mattress.[111] During the "slouched" placement, the "trunk" of the newborn-size sagittal device was flexed on average 47° compared to a flat mattress, and the "trunk" of an infant-size device flexed on average 49° compared to a flat mattress.[112]

38. Dr. Mannen and her team created this four-plane sagittal device.[113]

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[109] *See* CCX-1, pp. 34–35.
[110] CCX-1, p. 35.
[111] CCX-1, p. 35 (Table 1).
[112] CCX-1, p. 35 (Table 1).
[113] Aug. 7, 2023 Tr. 98:13–16.

39. Dr. Mannen does not state that the use of this device has been peer-reviewed. Nor has this testing technique been validated to correlate with human newborns or infants.

Head/Neck Flexion

40. To measure neck flexion, Dr. Mannen used newborn- and infant-sized CAMI dolls.[114]

41. Dr. Mannen's methodology is as follows: Dr. Mannen took the "neck" angle measurements of the CAMI dolls lying supine on a firm, flat surface to "provide the normalized head flexion values to which to compare." CCX-1, p. 20. *See id.*, p. 19 (Figure 5):

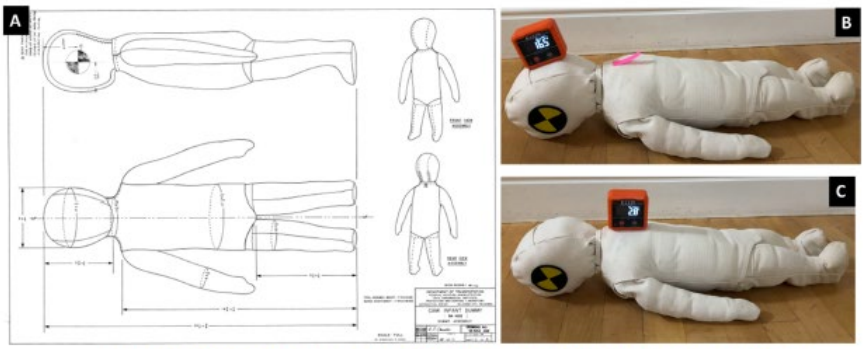


Figure 5. (A) Mechanical drawing and actual photos of the newborn CAMI dummy showing the (B) head angle and (C) torso angle during lying on a firm flat surface.

[114] Aug. 7, 2023 Tr. 111:22–112:4.

42. Then, Dr. Mannen placed each CAMI doll—newborn and infant sizes—in each of the ten Podsters, three times each in both the intended and slouched positions. CCX-1, p.20. *See id.* (Figure 6):

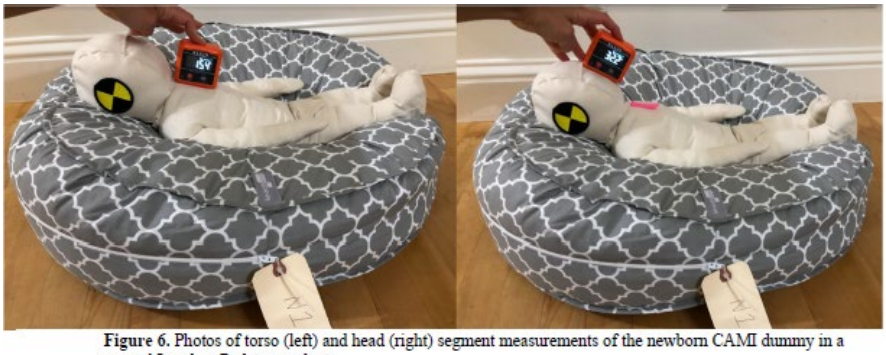


Figure 6. Photos of torso (left) and head (right) segment measurements of the newborn CAMI dummy in a normal Leachco Podster product.

43. At each placement, Dr. Mannen "calculated the increase in head flexion . . . compared to the normalized firm flat surface measurements."[115] As Dr. Mannen testified at the hearing, she measured the angle of the CAMI doll's head segment and the angle of the "rigid trunk segment" and then "compared those two measurements to find the angle between those two segments."[116]

44. Dr. Mannen acknowledged that a "real baby has trunk flexion."[117] Nonetheless, Dr. Mannen stated, when she's measuring for neck flexion, she's "not looking at the trunk flexion angle at all" because the CAMI doll's "trunk" segment is "rigid" and "not realistic."[118]

[115] CCX-1, p. 20.
[116] Aug. 7, 2023 Tr. 115:12–16.
[117] Aug. 7, 2023 Tr. 117:10.
[118] Aug. 7, 2023 Tr. 117:16–118:1.

45. The results of these comparison measurements were "presented in degrees and is normalized to the firm flat crib mattress condition, meaning this is the increase in head/neck flexion angle compared to the flat crib mattress condition." CCX-1, p. 37 (Table 2). *See id.*:

Pillow	Intended		Slouched	
	Newborn	Infant	Newborn	Infant
P1	37.8	34.2	57.5	62.6
P2	28.8	34.8	58.4	64.6
P3	35.0	31.7	58.3	61.8
P4	36.4	29.0	58.6	64.8
P5	33.6	25.8	57.4	62.4
N1	36.1	31.0	56.6	63.6
N2	30.9	30.3	59.0	60.7
N3	28.8	28.6	58.1	63.2
N4	35.0	28.4	58.0	62.0
N5	33.0	30.9	53.2	60.7
Mean	33.5	30.5	57.5	62.6
St Dev	3.2	2.7	1.7	1.4

46. Dr. Mannen had previously used the four-plane sagittal device to test head/neck flexion,[119] but she determined that this device did not accurately measure neck flexion.

47. CAMI dolls were designed for crash testing.[120]

48. To support her use of CAMI dolls for measuring neck flexion, Dr. Mannen cited a 1974 report prepared for the United States Department of Transportation.[121]

49. Dr. Mannen did not know whether this Chandler paper said anything about measuring neck angles with CAMI dolls, and Dr. Mannen is unaware of any peer-

[119] *See* CCX-1, Ex. B (Mannen 2019), Ex. C (Mannen 2022).
[120] Aug. 7, 2023 Tr. 112:12–15.
[121] CCX-1, p. 19 (citing 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).

reviewed study confirming the use of CAMI dolls to accurately measure neck angles.[122]

50. Dr. Mannen did not include any validation in her expert testimony showing that neck-angle measurements using CAMI dolls correlates with actual infants, and she cited to no peer-reviewed studies that have validated this method of testing infant or newborn neck angles.[123]

51. Accordingly, Dr. Mannen's expert report, CX-1, did not validate the results she took of the CAMI dolls to show that they correspond to how an infant's neck would actually be flexed in a Podster.[124]

52. Dr. Mannen testified that she is unaware of a device that can determine a threshold for safety with respect to neck flexion.[125]

53. Dr. Mannen testified that any neck angle above 0° "puts the baby at a higher risk for further flexion, which can be dangerous," that is creates a "higher risk that [a baby] can more easily achieve a neck flexion that will influence" breathing.[126]

54. Dr. Mannen states that medical literature says that a neck-flexion angle of 45° is dangerous.[127]

[122] Aug. 7, 2023 Tr. 113:8–17.
[123] Aug. 7, 2023 Tr. 113:18–114:4.
[124] Aug. 7, 2023 Tr. 114:5–8.
[125] Aug. 7, 2023 Tr. 110:12–15; 119:2–3.
[126] Aug. 7, 2023 Tr. 119:12–22.
[127] Aug. 7, 2023 Tr. 120:10–11; 121:7–16.

55. Dr. Mannen claims that any neck flexion is concerning because it takes less effort for a baby to go from 0° to 45° than it does from 1° to 45°.[128] Yet Dr. Mannen stated, "but practically does that one degree matter? Probably not."[129]

Infant Positioning—Dr. Mannen's Opinion

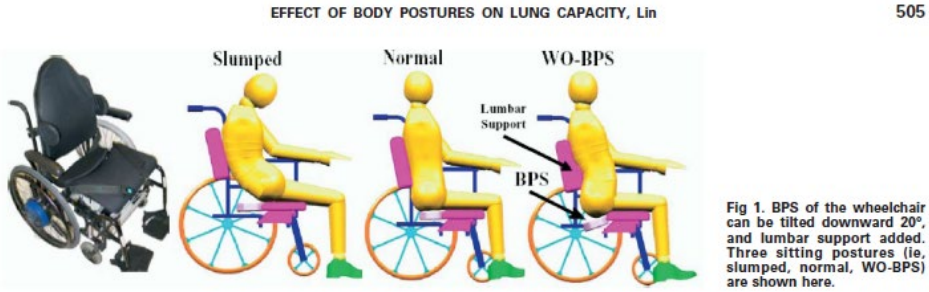
56. Dr. Mannen opines that the design of the Podster "[c]auses a flexed head/neck and flexed trunk posture during supine lying, inhibiting normal breathing."[130]

57. Again, Dr. Mannen's conclusions are based on comparisons. Here, Dr. Mannen states that the head/neck and trunk flexion are much higher for infants lying supine in the Podster "compared to a firm, flat crib mattress."[131] These results, Dr. Mannen opines, have "negative implications" for infant breathing.[132]

58. Dr. Mannen claims, "other researchers have reported that changes in trunk posture can negatively impact pulmonary and respiratory function."[133] Here, Dr. Mannen cites Lee 2010[134] and Lin 2006,[135] which were admitted into evidence as RX-30 (Lee 2010) and RX-31 (Lin 2006).

[128] Aug. 7, 2023 Tr. 120:11–15.
[129] Aug. 7, 2023 Tr. 120:20–22.
[130] CCX-1, pp. 6, 37 (footnote omitted).
[131] CCX-1, p. 38.
[132] CCX-1, p. 38.
[133] CCX-1, p. 39.
[134] 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.
[135] 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.

59. Dr. Mannen says that Lin 2006 found that a flexed-trunk posture during sitting, "not unlike" an infant's posture in a Podster, resulted in reduced lung capacity and lower expiratory flow—compared to a normal standing posture. CCX-1, p. 39. Lin 2006 studied live adults standing or sitting in a wheelchair in different positions—slumped forward, straight up, and with lumbar support. *See* RX-31, p. 002 (Figure 1):



60. These positions of live adults are different from the reclined position (of her sagittal-plane device) that Dr. Mannen tested in the Podster.

61. Lin 2006 concluded that measures of lung capacity and expiratory flow in the standing position were "significantly superior to show in clumped and normal sitting."[136]

62. Dr. Mannen further stated that Lee 2010 showed that slumped sitting posture "altered ribcage configuration and chest wall movements compared to normal sitting posture during breathing."[137] But, as Dr. Mannen admitted, Lee 2010 did not observe any breathing difficulties.[138]

[136] RX-31, p. 001.
[137] CCX-1, pp. 39–40.
[138] Aug. 7, 2023 Tr. 148:20–149:5.

63. Dr. Mannen relies heavily here on Mannen 2019.[139] But the Mannen 2019 study—which tested live infants on inclined sleep products—found no evidence that infants lying supine had oxygen-saturation problems.[140]

Facilitation of Rolling

64. Dr. Mannen opines that the Podster's design facilitates rolling on or off the product, which "can" lead to an infant's being in position where his nose and mouth or obstructed and/or he could experience rebreathing.[141]

65. According to Dr. Mannen, the body position of an infant lying in a Podster is "substantially similar" to lying in an inclined sleep product and, as a result, she can use the results from Mannen 2019 here.[142] Dr. Mannen acknowledged, however, that she has never observed an infant lying in a Podster.[143]

66. Dr. Mannen claims that on firm, flat mattresses, "some" types of rolling require first an increase in trunk and hip flexion, followed by rotation.[144] Further, since the Podster "already places an infant in a flexed trunk and hip flexion posture upon intended supine placement, the only additional movement that an infant must achieve is the rotation."[145]

67. Dr. Mannen relies on Kobayashi 2016.[146] Kobayashi 2016 was admitted into evidence as RX-29.

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[139] *See* CCX-1, pp. 38–40.
[140] Aug. 7, 2023 Tr. 111:9–18.
[141] CCX-1, p. 41.
[142] CCX-1, p. 41.
[143] Aug. 7, 2023 Tr. 126:8–13.
[144] CCX-1, p. 41.
[145] CCX-1, p. 41.
[146] 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. *See* CCX-1, p. 42.

68. According to Dr. Mannen, the "design of the Leachco Podster, like the inclined sleepers, subjects an infant to a flexed-hip and flexed-spine position, which then, based on published literature describing methods of infants achieving a roll (Kobayashi et al., 2016), would not have required the infant to coordinate as many movements to achieve a roll compared to a flat surface."[147]

69. Dr. Mannen states that infants can use several different approaches to initiate a roll, and "many" of these movements first require "a fully or partially flexed trunk and flexed-hip position."[148] As explained below (¶78), the latter part of this statement is not accurate.

70. Therefore, according to Dr. Mannen, the Podster reduces the coordinated movements required for rolling and thus makes it "easier" to roll in a Podster than on a firm, flat surface.[149]

71. But Dr. Mannen admitted at the hearing that she doesn't know how much easier it is to roll in a Podster compared to rolling on a firm, flat surface.[150]

72. Dr. Mannen asserts that she did not need to either conduct testing or cite rolling studies with live infants because she had Mannen 2019 to rely on.[151] She explained that she "did an analysis related to rolling based on the data from the 2019 study, but it didn't rely on infants actually rolling in the products because I could use the information I know about biomechanics and how infants roll . . . to understand

[147] CCX-1, p. 42.
[148] CCX-1, p. 42.
[149] CCX-1, pp. 42–43.
[150] Aug. 7, 2023 Tr. 140:3–8.
[151] Aug. 7, 2023 Tr. 140:12–22.

risk, and facilitation of rolling."[152] She did not observe any infants rolling in any of the inclined sleep products during the Mannen 2019 study.[153]

73. Dr. Mannen provides a figure of a roll from Kobayashi 2016; *see* CCX-1, p. 42:

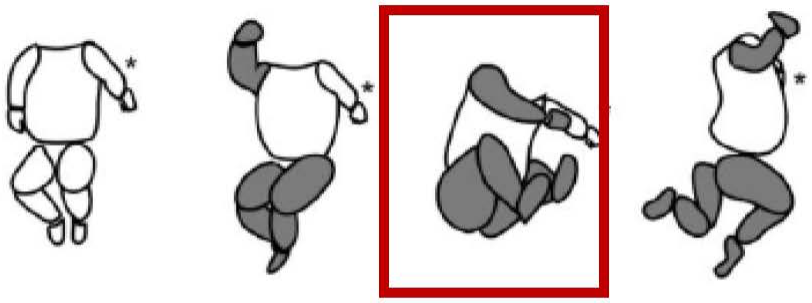

Figure 14. Figure showing a four-step rolling technique (from left to right) which requires coordinated movements where the flexed trunk and flexed hip position (third step, red box) is an intermediate step to complete the rolling task. The Leachco Podster puts an infant in this flexed-hip position, eliminating otherwise necessary coordinated movements required to achieve a roll (Kobayashi et al, 2016).

74. Kobayashi 2016 did not study rolling on inclined products; the infants were observed rolling on flat surfaces.[154]

75. Kobayashi 2016 studied two groups of infants: "younger" infants (aged 5–7 months) and "older" infants (8–10 months).[155]

[152] Aug. 7, 2023 Tr. 141:15–22.
[153] Aug. 7, 2023 Tr. 142:1–4.
[154] *See* RX-29, p. 003.
[155] RX-29, p. 001; Aug. 7, 2023 Tr. 143:15–19.

76. The "rolling" figure from Kobayashi 2016 that Dr. Mannen included in her expert report—pattern 8C[156]—is one of six rolling patterns identified by Kobayashi 2016. *See* RX-29, p. 010, as shown here:

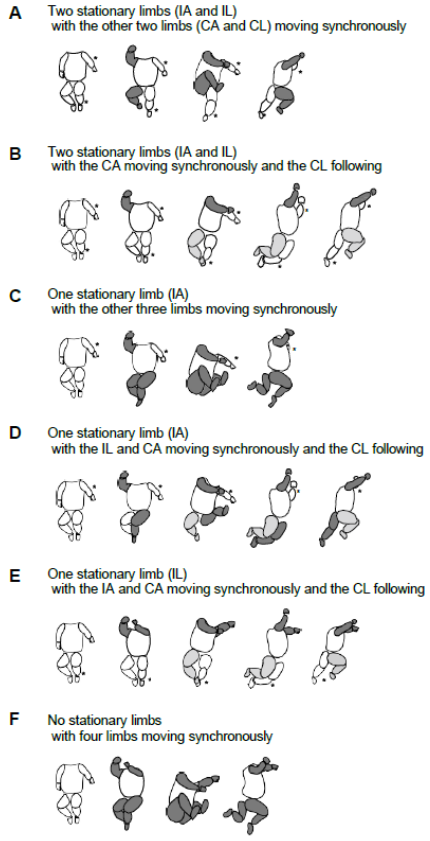

Fig. 8 The serial order of highly observed movement patterns of rolling in infants. Rollings to the *left* are illustrated based on the video data. The limbs indicated with an asterisk are the stationary limbs. The limbs colored *dark gray* represent the synchronous limbs with respect to the movement of the trunk (TR). The limbs colored light gray represent the following limbs

77. According to Kobayashi 2016, these six patters are the "highly observed movement patterns of rolling in infants."[157] And the patterns are arranged from most common (8A) to least common (8F).[158]

[156] CCX-1, p. 42
[157] RX-29, p. 010. *See* Aug. 7, 2023 Tr. 145:1–7.
[158] RX-29, p. 010. *See* Aug. 7, 2023 Tr. 145:1–7.

78. Of the six patterns, only two—8C and 8F—show an infant using the fetal tuck position that Dr. Mannen opined makes it easier for infants to roll.[159] (That four of the six highly observed rolling patterns do not require the fetal tuck position undermines Dr. Mannen's statement above (¶69) that "many" of these movements first require "a fully or partially flexed trunk and flexed-hip position").

79. Further, patterns 8C and 8F were most observed among the older infants (aged 8–10 months).[160] Indeed, the most highly observed pattern in older infants was the ones shown in figure 8C—the only rolling pattern that Dr. Mannen identified in her expert report.[161]

80. Dr. Mannen acknowledged that the older infants studied in Kobayashi 2016 were too old for the Podster.[162]

Muscle Fatigue and Ability to Self-Rescue

81. Dr. Mannen opines that the Podster's design causes abdominal muscle fatigue and "negative affects" an infant's ability to self-rescue if an infant is in a position in which the infant's nose and mouth are obstructed.[163]

82. Here, Dr. Mannen did not conduct new tests, and she did not observe infants in the Podster. Rather, she relies primarily on Mannen 2019 and two published papers she co-authored: Wang 2020[164] (admitted into evidence as RX-34) and Wang

[159] RX-29, p. 010. *See* Aug. 7, 2023 Tr. 145:11–15.
[160] RX-29, pp. 010–011; *see* Aug. 7, 2023 Tr. 146:15–147:16.
[161] RX-29, p. 011; CCX-1, p. 42; Aug. 7, 2023 Tr. 147:9–11.
[162] Aug. 7, 2023 Tr. 144:3–7.
[163] CCX-1, pp. 44–46.
[164] 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.

2021[165] (admitted into evidence as RX-35). Wang 2020 compared the muscle activity of live infants on inclined-crib mattress (0° vs. 10° v. 20°).[166] Wang 2021 used motion capture and electromyography tools to measure infants in three inclined sleeper products.[167] Dr. Mannen claims that the results from these papers can be applied to the Podster.[168]

83. Dr. Mannen writes that, according to Mannen 2019, infants lying prone on a product "like" a Podster experience "up to 2.5 times more abdominal muscle activity compared to lying on a firm, flat mattress . . . ."[169] According to Dr. Mannen, this comparison "means that infants are now recruiting muscles that facilitate breathing for movement as well, meaning these muscles vital to breathing will fatigue more quickly, which can lead to a dangerous suffocation situation."[170]

84. Dr. Mannen quotes from Wang 2021 to state that "'the lack of firmness or the presence of extra padding in the sleep surface alters an infant's ability to move which *could* contribute to the increased risk of suffocation *if* an infant struggles to move into a safe breathing position;'" and "'the combination of incline angle and product design requires infants to use significantly more core effort (abdominal strength) to maintain a prone position *compared to* lying on a flat surface. *If* an infant achieves a roll from supine to prone within an inclined sleep product, the limited horizontal

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[165] Wang J, Siddicky SF, Carroll JL, Rabenhorst BM, Bumpass DB, Whitaker BN, Mannen EM. 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.
[166] *See* RX-34, p. 001.
[167] *See* RX-35, p. 004.
[168] CCX-1, p. 44.
[169] CCX-1, p. 44.
[170] CCX-1, p. 44.

space and pliant concave surface *likely* makes rolling prone to supine difficult or impossible. Therefore, infants attempt to maintain a safe prone posture to facilitate breathing, which places an increased demand on the core muscles as suggested by the EMG [muscle activity] results.'"[171]

85. Dr. Mannen opines, "when an infant rolls from supine to prone on a Leachco Podster, an infant will experience significant biomechanical challenges."[172]

86. Further, Dr. Mannen opines: "If an infant becomes fatigued while lying prone on the product before a caregiver recognizes the problem, the infant therefore is at high risk for suffocation."[173]

87. Once more: "If the Leachco Podster is placed on a surface with plush soft goods like an adult bed, an infant rolling from supine onto the adult bed would produce similar concerning suffocation hazards. Loose bedding is a known suffocation hazard for infants, so if the Leachco Podster pillow facilitates rolling from the pillow onto an unsafe sleep space, an infant is subjected to increased risk of death."[174]

88. But Wang 2021 states: "It is likely that infants in the prone position within an inclined sleep product with increased abdominal muscle activity also have restricted rib cage expansion and may be at further risk for hypoxemia. However, the relationship between infant body position and breathing must be further explored."[175]

[171] CCX-1, pp. 44–45 (emphasis added).
[172] CCX-1, p. 45.
[173] CCX-1, p. 46.
[174] CCX-1, p. 46.
[175] RX-35, p. 007.

Firmness

89. Dr. Mannen opines that a product that is "too soft" will deform "too much" and envelop an infant's face if the infant is prone or if her face is pressed against the side of a product.[176]

90. For this test, Dr. Mannen developed a "vertical lifter device" that measures vertical displacement at a vertically applied 10 Newton (10N) load.[177]

91. According to Dr. Mannen, the "vertical displacement for crib mattresses, which are considered a safe location for infant sleep, was 0.71″±0.25″. A threshold of <1″ displacement at a 10N load was therefore used as a control because that would approximate the safe degree of displacement present in a typical crib mattress."[178]

92. Dr. Mannen used this test method three times on each of the ten Podsters.[179] She measured displacement during each test. She then calculated the mean and standard deviations, and statistically compared the standard versus plush Leachco Podster products (t-test, $p<0.05$). These values were then compared with displacements measured on the crib mattresses.[180]

93. According to Dr. Mannen, the Podsters failed all tests.[181]

94. Dr. Mannen opines that, therefore, the Podster is "too soft for an infant to safely use, because, depending on the infant's position, the product can (a) conform

[176] CCX-1, p. 21.
[177] CCX-1, p. 23.
[178] CCX-1, p. 23.
[179] CCX-1, pp. 23–24.
[180] CCX-1, p. 24.
[181] CCX-1, p. 46.

an infant's nose and mouth and (b) make it more difficult for an infant to self-rescue."[182]

95. Also, Dr. Mannen states that the Podsters are "significantly softer" than crib mattresses.[183]

Airflow

96. Dr. Mannen opines that airflow testing can tell how easy it is for air to flow through a product.[184] According to Dr. Mannen, a product with "appropriate airflow" means that "the work of breathing would not increase when the infant breathes into the product," while a product "without appropriate airflow" means that an infant "would require increased work to achieve the exchange of air required for respiration."[185]

[182] CCX-1, pp. 46–47.
[183] CCX-1, p. 47.
[184] CCX-1, p. 24.
[185] CCX-1, p. 24.

97. To conduct testing, Dr. Mannen used a device developed for the Mannen 2022-CPSC study. This device was based on BS 4578:1970, modified to "include physiologically accurate volumetric flow rate (2 L/min) and probe (3″ hemisphere (representative of the mouth), 3 mm nares (representative of the nostrils)."[186] *See id.*, p. 26 (Figure 9):

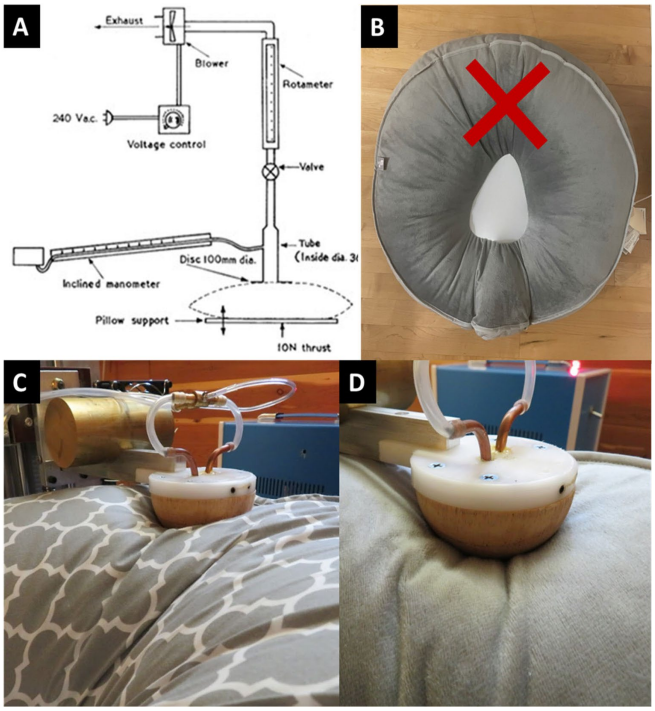

Figure 9. Depiction of (A) airflow testing schematic from BS 4578:1970, and modified test being conducted at (B) the location of intended head placement marked with the red x on (C) a standard Leachco Podster product and (D) a plush Leachco Podster product.

98. The device did not have a three-dimensional shape, as a baby's head would. And, as observed in Mannen 2022 (which Dr. Mannen relies on here), "full occlusion is more likely" to be found in this test than "in a real-life scenario."[187]

[186] CCX-1, p. 25.
[187] CCX-1, Ex. C, p. 246.

99. Dr. Mannen tested the maximum-thickness portion of the ten Podsters three times each.[188]

100. She then calculated means and standard deviations and statistically compared the standard vs. plush results (t-test, $p<0.05$).[189]

101. Dr. Mannen refers to Mannen 2022, which (Dr. Mannen says) "established that mesh-like airflow represents a condition where air can flow freely through material."[190] Mannen 2022 "established that a pressure of less than 0.31 inches of water (in H_2O; this is a unit of pressure) . . . was an appropriate threshold to ensure safety." *Id*. This "threshold" was determined by comparing airflow-test results of crib bumpers, which had apparently been associated with fatalities, and mesh liner products, which—based on data from unpublished research—"are not known to have resulted in fatalities."[191]

102. Neither Mannen 2022 nor Dr. Mannen's expert report here identifies a safety threshold other than based on a comparison of two products.[192]

103. Mannen 2022 further states:

> The 0.31 in. H_2O is three standard deviations above (i.e., less conservative than) the mesh liner airflow results (Section 4). We note that many prone-lying suffocation incidents we reviewed occurred in lounger product P04 included in our study, which we found to have low airflow, with pressure values of 3.6 in. H_2O. Suffocation

[188] CCX-1, p. 25.
[189] CCX-1, p. 25.
[190] CCX-1, p. 25.
[191] CCX-1, Ex. C (Mannen 2022), pp. 215, 221.
[192] *See, e.g.*, CCX-1, Ex. C (Mannen 2022), p. 224 ("For airflow testing, a threshold of 0.31 in. H_2O provides a conservative target value to ensure mesh-like airflow, which is unlikely to pose a hazard from a suffocation or rebreathing perspective."); *id*., p. 246 ("We recognize that the 0.31 in. H_2O mesh-like airflow threshold may be conservative as it is based on mesh liner results, and that there is *likely* a small range of airflow values higher than this threshold which *may not* pose a suffocation or rebreathing danger for the baby.").

> incidents also occurred in various models of nursing product P14, which featured a much higher airflow, with pressure values approximately 0.93 in. H_2O. Thus, we do believe that the safe range of airflow as measured by pressure drop must be below this 0.93 H_2O threshold, where many suffocation incidents have occurred. However, *our testing and the available literature do not adequately define what upper limit is safe*.[193]

104. According to Dr. Mannen, the test results show that the Podsters exhibited over 10 times less airflow compared to a recommended threshold identified in Mannen 2023.[194] Dr. Mannen opined that the Podsters "significantly inhibited normal airflow."[195] And Dr. Mannen asserts that "if an infant was breathing into" a Podster, the infant would require "significantly more work to breathe."[196]

Rebreathing

105. The term "rebreathing" here refers to a situation in which air can pass through a product, but because CO_2 may "pool" within a product, an infant may "rebreathe" CO_2 that the infant had breathed out.[197] At some point, an infant can "rebreathe" "too much" CO_2.[198]

106. Dr. Mannen tested the ten Podsters one time each and tested a crib mattress with a cotton sheet (also once), using methods developed in Carleton 1998 and modified by Maltese & Leshner 2019.[199] The Carleton 1998 paper was admitted into evidence as RX-28; Maltese & Leshner 2019 was admitted into evidence as RX-32.

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[193] CCX-1, Ex. C (Mannen 2022), pp. 246–47 (emphasis added).
[194] CCX-1, p. 48.
[195] CCX-1, p. 48.
[196] CCX-1, p. 48–49.
[197] CCX-1, p. 27.
[198] *Id*. *See also* Aug. 7, 2023 Tr. 131:5–13.
[199] CCX-1, pp. 27–28, 49; Aug. 7, 2023 Tr. 131:14–16; 135:4–7.

107. A doll with tubing through the nostrils was placed face down on the Podster and a mattress, and Dr. Mannen conducted one test on each Podster and one on a mattress for concentration of CO_2.[200] No testing was done while the doll was on its side or in any position other than prone.[201]

108. According to Dr. Mannen, the purpose of the test was to determine if there's an abnormal exchange of gases.[202]

109. Dr. Mannen testified that for a risk to exist, a product must retain or pool CO_2.[203] But Dr. Mannen did not test how much CO_2 a Podster could retain or pool.[204]

110. Dr. Mannen used a mattress (with a cotton sheet) as a baseline measurement.[205]

111. Dr. Mannen reports that CO_2 increased from 5.6% CO_2 on the crib mattress with a sheet to 13.7% CO_2 on the Leachco Podsters, *an increase of nearly 2.5 times*," and "O_2 inhalation decreased from 19.6% in the crib mattress condition to 17.8% on average in the Leachco Podsters."[206]

112. According to Dr. Mannen, these results show that, "if an infant breathes into the Leachco Podster, the O_2 decreases and the CO_2 substantially increases, increasing the risk for hypoxia (not breathing enough oxygen) and breathing in too much CO_2."[207]

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[200] CCX-1, p. 28; Aug. 7, 2023 Tr. 134:16–22.
[201] Aug. 7, 2023 Tr. 135:1–3.
[202] Aug. 7, 2023 Tr. 132:3–5.
[203] Aug. 7, 2023 Tr. 133:17–19.
[204] Aug. 7, 2023 Tr. 134:1–5.
[205] CCX-1, p. 27–28, 49; Aug. 7, 2023 Tr. 134:6–15.
[206] CCX-1, p. 49.
[207] CCX-1, pp. 49–50 (citing Expert Testimony of Kr. Katwa).

113. For her expert report here, CX-1, Dr. Mannen did not perform any tests on live infants.[208]

114. And Dr. Mannen's 2019 CPSC study, which involved the testing of live infants, found that no infant lying in a supine position in an inclined-sleep product had oxygen-saturation problems.[209]

115. Dr. Mannen did not validate her test results for live infants. She said that the model "does its best to mimic inhalation, exhalation, and the gasses that are exhaled."[210] But it's "not a perfect model," which is "why it was important to compare" the Podster test results to the "crib mattress condition."[211]

116. The Carleton 1998 paper states that "[b]ecause the model cannot physically respond to increased CO_2 like an infant (the model's breathing rate and volume are fixed), CO_2 rapidly equilibrates in the trachea in concentrations that probably exaggerate the effect an infant would experience."[212]

117. The Carleton 1998 paper also states that "[i]t would not be appropriate to speculate on the role that rebreathing might have played in any specific case, based solely upon these results."[213]

118. Further, according to Maltese & Leshner 2019, "Our research is subject to certain limitations. First, the mechanical compliance (stiffness) of the ARS face has not been shown to have fidelity to the human infant, nor has the variability in human

[208] Aug. 7, 2023 Tr. 111:19–21.
[209] Aug. 7, 2023 Tr. 111:9–12, 18.
[210] Aug. 7, 2023 Tr. 135:15–20.
[211] Aug. 7, 2023 Tr. 135:20–22.
[212] RX-28, p. 004. *See* Aug. 7, 2023 Tr. 136:4–22.
[213] RX-28, p. 005. *See* Aug. 7, 2023 Tr. 137:1–12.

facial anthropometry been examined; both of these factors may influence the interaction between the face and the sample."[214] Maltese & Leshner 2019 also states, "without additional research, none of the CO_2RB [CO_2 Re-Breathing] values reported herein should be interpreted as that which would be expected in a human infant."[215]

119. Dr. Mannen did not conduct additional research to determine whether the results of the Carleton 1998 / Maltese & Leshner 2019 methods she used could be interpreted as that which would be expected in a human infant.[216] According to Dr. Mannen, she did not need to do additional research because she "wasn't relying on the actual values, just as [Maltese & Leshner 2019] says."[217]

120. Dr. Mannen relied solely on the comparison between the test results of the Podster and the test result of the crib mattress.[218]

121. Dr. Mannen does not know how much rebreathing is "too much" to be dangerous.[219]

Head Rotation

122. Dr. Mannen opined that the Podster's concave shape and high sides make it more likely that an infant's nose and mouth will come into contact with the Podster's sides, which—compared to an infant lying on firm, flat mattress—increases the risk for airflow and rebreathing.[220]

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[214] RX-32, pp. 006–007.
[215] RX-32, p. 007. *See also* Aug. 7, 2023 Tr. 137:13–138:16.
[216] Aug. 7, 2023 Tr. 138:17–21.
[217] Aug. 7, 2023 Tr. 138:21–22.
[218] Aug. 7, 2023 Tr. 139:2–3.
[219] Aug. 7, 2023 Tr. 139:5–19.
[220] CCX-1, pp. 25–26, 28–29.

123. Dr. Mannen used CAMI dolls to measure head rotation to determine whether an infant's face would be in contact with the Podster's sides when an infant, lying supine or prone, is in either the intended or slouched position.[221]

124. To conduct these measurements, Dr. Mannen placed newborn- and infant-sized CAMI dolls, supine, in intended and slouched positions.[222] She then rotated the CAMI doll's head 90° and measured the distance from the CAMI doll's "nose/mouth" to the side of the Podster.[223] She did each position three times in each of the ten Podsters.[224] *See id*, p. 30 (Figure 11):

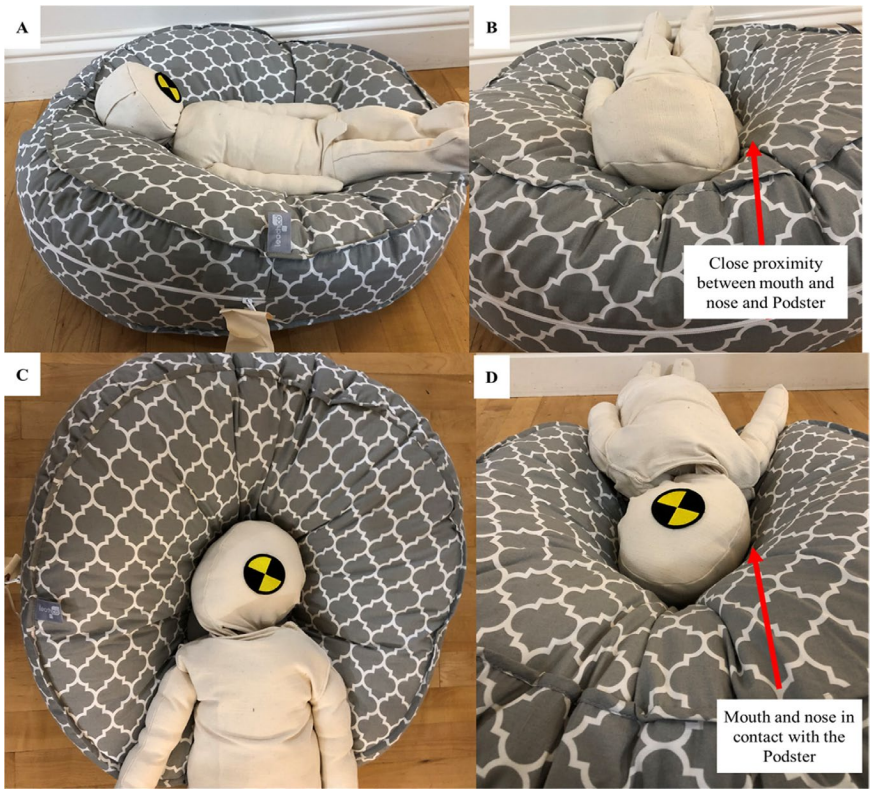

Figure 11. Photos of the head rotation testing with the newborn-sized CAMI dunny during supine lying with a 90° head turn in the (A) and (B) intended position and (C) and (D) slouched scenario on standard product.

[221] CCX-1, pp. 29-30.
[222] CCX-1, pp. 29–30.
[223] CCX-1, pp. 29-30; Aug. 7, 2023 Tr. 122:2–11.
[224] CCX-1, pp. 29–30.

125. Dr. Mannen testified that she does not know how close to a product a baby's face needs to be before a rebreathing danger arises.[225]

126. Dr. Mannen testified that, while her report includes the distances measured between the nose/mouth "region" of the CAMI dolls and the Podster, this test was essentially a pass/fail test—if the nose/mouth of the CAMI doll was not in contact with the Podster, the Podster passed the test.[226]

127. The results of Dr. Mannen's expert report show that when the CAMI dolls, both infant- and newborn-sized, were in the *intended* position, there was no contact between the CAMI doll's nose/mouth region and the Podster.[227] *See* CCX-1, p. 52 (Table 4):

Pillow	Newborn	Infant
N1	2.8	2.2
N2	0.4	1.2
N3	0.7	1.8
N4	3.5	2.8
N5	1.6	0.5
P1	0.3	0.7
P2	0.8	0.5
P3	2.7	0.3
P4	0.7	1.6
P5	0.9	1.5

Table 4. Mean distances (cm) from the mouth and nose of the newborn-sized and infant-sized CAMI doll during supine lying in the intended position with a 90° head rotation. A value of "0" means the infant's mouth or nose would be in contact with the soft surface of the pillow. Values from the slouched position are not listed because in all instances the mouth and nose were in contact with the soft sides of the product.

[225] Aug. 7, 2023 Tr. 123:9–124:2.
[226] Aug. 7, 2023 Tr. 122:13–22. *See* Aug. 9, 2023 Tr. 41:1–4 (Dr. Katwa's testifying that if the nose and mouth are not obstructed, then no risk of rebreathing exists).
[227] CCX-1, p. 52; Aug. 7, 2023 Tr. 125:6–20; 163:19–20.

128. Dr. Mannen opined that a 90° head rotation of an infant in a *slouched* position results in nose/mouth contact with the Podster.[228]

129. Dr. Mannen's report includes a "schematic drawing"[229], purporting to compare 90° head rotations between a firm flat mattress and the Podster:

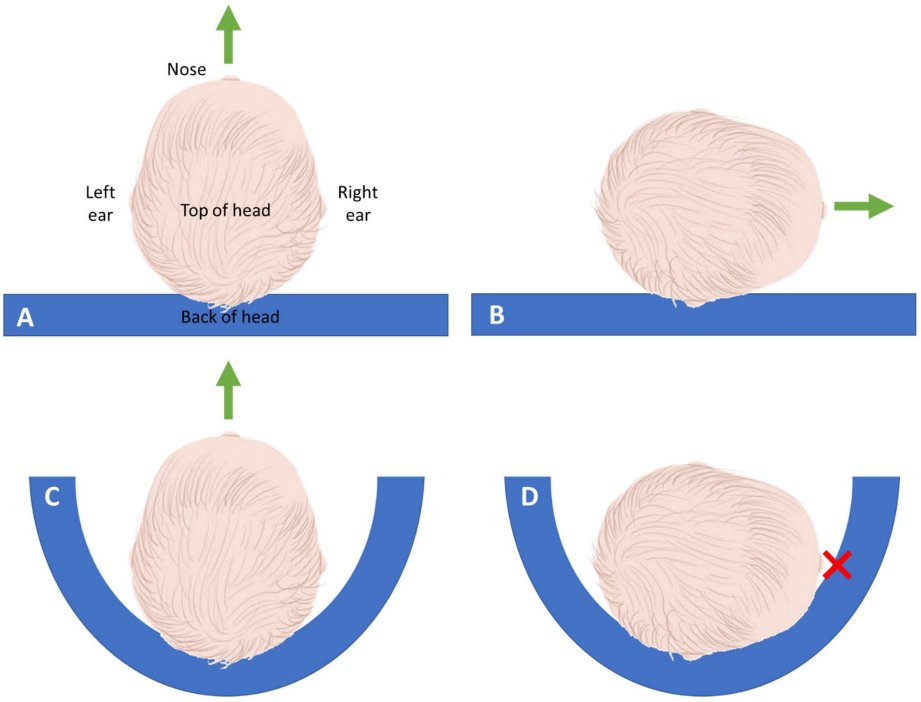

Figure 17. Schematic drawing from the top of the head looking down, where the green arrows or red x represent the nose and mouth region, depicting an infant lying supine (A) on a crib mattress with no head rotation, (B) on a crib mattress with a 90° head rotation, (C) on a soft and conforming product, such as the Podster, with no head rotation, and (D) on a soft and conforming product, such as the Podster, with 90° head rotation depicting the nose and mouth region in direct contact with the soft side of the product, creating a serious suffocation and CO_2 rebreathing hazard.

130. The Court finds this "schematic" to be misleading, as real Podsters do not have a semi-circular shape, as depicted in (C) and (D) here. (Figure 17). If anything, the schematic (D) shows that the nose and mouth are not in contact with the sides.

[228] CCX-1, p. 53.
[229] CCX-1, p. 54 (Figure 17)

131. Dr. Mannen also took head-rotation measurements of the CAMI dolls in the prone position.[230] Here, she "located the mouth/nose region" of the CAMI doll and then measured the head rotation "required to visually free the mouth/nose region from the surface" of the Podster.[231] She conducted this measurement with both the newborn- and infant-sized CAMI dolls three times each in the ten Podsters—and then compared the results to measurements taken on a firm flat surface that "serve[d] as a control."[232] *See id.* (Figure 12):

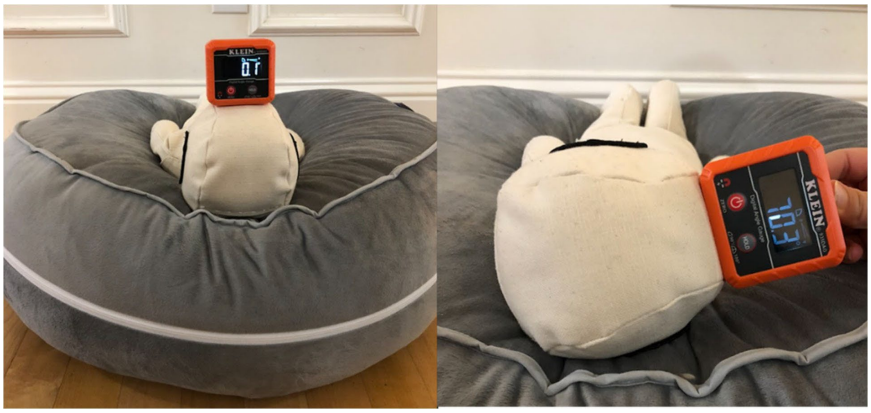

Figure 12. Photos from testing of the head rotation required during prone lying to free the mouth/nose region of the CAMI dummy to allow for free airflow.

132. Here, Dr. Mannen compared the head rotation "required" to enable an infant to breathe freely (a) while lying prone on a firm, flat mattress or (b) while lying prone in a Podster.[233]

133. According to Dr. Mannen's report, a newborn-sized CAMI doll lying prone on a flat crib mattress with a fitted cotton sheet must rotate its head only 10°, and an infant-sized CAMI doll only 15°, to free its "mouth/nose region" from obstruction.[234]

[230] CCX-1, pp. 30–31.
[231] CCX-1, p. 31.
[232] CCX-1, p. 31.
[233] CCX-1, pp. 55–56.
[234] CCX-1, p. 55.

134. In comparison, a newborn-sized CAMI doll lying prone in a Podster must rotate its head (on average) 47.5°, and an infant-sized CAMI doll 56.2°, to free its "mouth/nose region" from obstruction.[235]

135. Dr. Mannen testified that her head-rotation test is a "valid test to show how an infant's normal interaction with the product influences the risk that [an infant] will come into contact" with the product.[236] But Dr. Mannen admitted that she turned the CAMI dolls' heads for purposes of her test; that she has never seen how an infant normally interacts with the Podster; and that she discusses the "normal" range of motion in her report—but not in a Podster.[237]

136. The Mannen 2023 study used this head-rotation test.[238] In this 2023 study, Dr. Mannen and her team concluded: "While this head rotation test is interesting and the test methodology is simple, a less subjective test with a well-defined threshold for safety related to the risk that an infant's mouth/nose will contact a plush product may be a better option."[239]

c. The methods employed by Dr. Mannen and the test results do not support Dr. Mannen's broad conclusions.

137. First, as discussed more below, many of Dr. Mannen's tests involved mere comparisons, and her test results showed what happened on a Podster relative to what happened on a firm, flat mattress. But Dr. Mannen failed to identify safety/ danger thresholds—with the exception of neck-flexion angles (discussed below at

[235] CCX-1, p. 55.
[236] Aug. 7, 2023 Tr. 128:3–6.
[237] Aug. 7, 2023 Tr. 128:15–129:10.
[238] RX-36, pp. 060–066.
[239] RX-36, p. 065.

¶¶162–163). These "comparison" methodologies and results do not satisfy the *Daubert* standard.

138. In *Rovid v. Graco Children's Products Inc.*, the court excluded expert testimony because, among other things, the expert merely compared results without identifying thresholds. No. 17-cv-01506-PJH, 2018 WL 5906075, at *7 (N.D. Cal. Nov. 9, 2018). According to the court, the testimony there was improperly "limited to showing the [Podster's] performance in the tests *relative* to . . . mattresses' performance." *Id*.

139. Here, Dr. Mannen's testimony about airflow, rebreathing, and firmness[240] is similarly "limited to showing the [Podster's] performance in the tests *relative* to . . . mattresses' performance." *Id*. And, likewise, Dr. Mannen's testimony about neck flexion, trunk flexion, rolling, and muscle fatigue[241] is limited to looking at results found in the Podster *compared to* results from testing on a mattress. *See Rovid*, 2018 WL 5906075, at *7.

140. Notably, the expert in *Rovid* was Michael Leshner—the same person whose methods Dr. Mannen followed to conduct her rebreathing analysis.[242] Like Dr. Mannen here,[243] Leshner studied how the subject product and "exemplar" products (mattresses) "compared to other similar infant sleep surfaces in a carbon dioxide rebreathing performance test." *Rovid*, 2018 WL 5906075, at *4.

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[240] *See above*, Proposed Conclusions of Law ¶¶89–121.
[241] *See above*, Proposed Conclusions of Law ¶¶32–88.
[242] *See* CCX-1, p. 27 ("I tested each of the 10 Leachco Podster pillows . . . and a crib mattress with a cotton sheet using methods developed by Carleton et al. (1998) and modified by [RX-32] Maltese and Leshner (2019)."); Aug. 7, 2023 Tr. 131:14–16; 135:4–7.
[243] *See above*, Proposed Conclusions of Law ¶¶81–95.

141. Just like Dr. Mannen,[244] Leshner "[did] not explain how these [test-result] values correlate to what a live infant would experience. Nor [did] he explain what objective standard these values should be compared against—*i.e.*, Leshner [did] not explain what a dangerous or safe %CO2 level reading would be." *Rovid*, 2018 WL 5906075, at *4.

142. Again, like Dr. Mannen,[245] Leshner attempted to opine about whether a product's "permeability" rebreathing performance. The court noted, "importantly, Leshner is not a medical expert qualified to testify about SIDS or rebreathing-related asphyxiation." *Rovid*, 2018 WL 5906075, at *5.

143. Just like Dr. Mannen,[246] "Leshner did not test for whether a mattress' propensity to store gas, as opposed to some other design feature, caused the elevated %CO2 results." *Rovid*, 2018 WL 5906075, at *5.

144. The court in *Rovid* held that Leshner's report had to be excluded and that his testimony was neither (1) reliable nor (2) relevant. *Rovid*, 2018 WL 5906075, at *5.

145. The court found Leshner's methodology problematic because, like Dr. Mannen,[247] he tested each product only once. *Rovid*, 2018 WL 5906075, at *5.

146. The Maltese & Leshner 2019 paper noted that, "without additional research, none of the CO_2RB [CO_2 Re-Breathing] values reported herein should be

[244] *See above*, Proposed Conclusions of Law ¶120.
[245] *See above*, Proposed Conclusions of Law ¶¶106–122.
[246] *See above*, Proposed Conclusions of Law ¶110.
[247] CCX-1, pp. 27–28, 49; Aug. 7, 2023 Tr. 131:14–16; 135:4–7.

interpreted as that which would be expected in a human infant."[248] Dr. Mannen claimed that she did not need to do this additional research because she was merely comparing results; she "wasn't relying on the actual values, just as [Maltese & Leshner 2019] says."[249]

147. Further, the goal of *Daubert's* "gatekeeping requirement" is to "ensure the reliability and relevancy of expert testimony. It is to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

148. Here, for the most part, Dr. Mannen relied on, and followed the methodologies from, three non-peer-reviewed studies that she carried out for the CPSC.[250]

149. The methodologies from papers that Dr. Mannen used for her expert report have not been validated in peer-reviewed studies.

150. For example, as noted above, to measure trunk flexion Dr. Mannen used a four-plane sagittal device, that has not been validated.[251] And, in the recent study Dr. Mannen led on behalf of the CPSC—Mannen 2023—her team used a new, *five*-segment sagittal device.[252] According to the Mannen 2023 study, "Our five-segment sagittal plane testing device *is progressing toward becoming* a valid measurement tool to estimate body position, but further research is required to improve the head-neck flexion results *and to determine thresholds for safety*."[253] Dr. Mannen's supposedly

[248] RX-32, p. 007. *See also* Aug. 7, 2023 Tr. 137:13–138:16.
[249] Aug. 7, 2023 Tr. 138:21–22.
[250] Aug. 7, 2023 Tr. 83:22–85:4.
[251] *See above*, Proposed Conclusions of Law ¶¶39–40.
[252] *See* Aug. 7, 2023 Tr. 107:8–20; RX-36 (Mannen 2023).
[253] RX-36, p. 200 (emphasis added).

improved five-segment device itself still needs to be improved before it can be an accepted scientific tool.

151. Dr. Mannen also relied on two peer-reviewed papers, of which she was a co-author for her testimony about muscle fatigue.[254] But one of those papers—Wang 2021—used motion capture and electromyography tools to measure infants in three inclined sleeper products—tools that were not used for Dr. Mannen's expert report.[255] Further, both Wang 2020 and Wang 2021, like many of Dr. Madden's tests here, "compared between the firm flat crib mattress" and other products.[256]

152. Further, the lack of fit between Dr. Mannen's expert testimony here and Mannen 2019, Mannen 2022, and Mannen 2023, is supported by Dr. Mannen's testimony.

a. Her report relied on a peer-reviewed study of which she was a co-author.[257]

b. This Wang 2021 study looked at body movement and muscle activity of healthy infants lying supine and prone in three different inclined sleep products.[258]

c. Importantly, the authors (Dr. Mannen included) of this study could not compare the results among the three different products because they had not created a statistical design to do so.[259]

d. For her expert testimony here, Dr. Mannen likewise did not create a statistical design to compare her results to the results from other studies or products.

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[254] *See above*, Proposed Conclusions of Law ¶83.
[255] *See* RX-35, p. 004; Aug. 7, 2023 Tr. 80:14–17; *see id.*, 160:10–17; 166:11–16 (describing motion-capture and electromyography sensors on live infants for Mannen 2019—methods that were not used for Dr. Mannen's expert report).
[256] Aug. 7, 2023 Tr. 86:11–12; *see also* RX-34, p. 001.
[257] RX-35 (Wang 2021). *See* CCX-1, p. 66.
[258] RX-35; *see* Aug. 7, 2023 Tr. 86:1–8.
[259] Aug. 7, 2023 Tr. 86:1–12; *see id.*, 97:8–98:6.

e. Therefore, to repeat, the Court will not consider the results from Mannen 2019, Mannen 2022, and Mannen 2023 when deciding whether the Podster is defective.

153. Thus, the Court finds that Dr. Manned failed to "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

154. Dr. Mannen's measurements also depended on *her* placement of either the sagittal-plane device (trunk flexion), CAMI dummy (neck flexion and head rotation), or doll (rebreathing). Dr. Mannen did not explain how she ensured that her placements were standard or repeatable; nor did she explain how her placements controlled for various factors, *e.g.*, the pressure she used to push a CAMI doll into place.[260] While the Court does not suggest that Dr. Mannen attempted to manipulate the test devices to achieve certain results, her subjective placements do not ensure scientifically rigorous practices. *Compare Rovid*, 2018 WL 5906075, at *7 ("That [failure to control for the position or to repeat his testing] highlights the inadequacy of Leshner's testing. It is exactly because very high readings can occur that scientific rigor requires multiple tests and requires the control of certain variables—such as the positioning of the doll.").

155. But, as in *Rovid*, even if Dr. Mannen's methodologies weren't problematic, her tests and test results do not support her broad conclusions. *See Rovid*, 2018 WL 5906075, at *7 (citing *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

[260] *See* CCX-48 (video of Dr. Mannen explaining test for neck flexion), beginning at approximately 1:19 (showing Dr. Mannen pushing CAMI doll into position).

156. Leshner's formal conclusions were limited to rebreathing tests across different products, while Dr. Mannen performed more tests. Nonetheless, Leshner's conclusions mirror Dr. Mannen's. Here are Leshner's conclusions:

> 1. Among the play yard mattresses tested, the [company's] mattresses produced the highest and most hazardous concentration of CO2 rebreathing in the test series;
>
> 2. The subject [defendant's] mattress produced a level of CO_2 rebreathing similar to infant products that have been banned as potentially hazardous;
>
> 3. Sleep surfaces producing high levels of CO_2 rebreathing in the infant model are expected to produce a similar result in live infants, and;
>
> 4. The subject mattress and similar exemplars are hazardous to infants and defective in design.

Rovid, 2018 WL 5906075, at *5.

157. As the court in *Rovid* explained, the problems with Leshner's testimony was that it was "limited to showing the subject mattress performance in the tests *relative* to the other mattresses' performance," and, "independently fatal," Leshner's results did "not support his conclusions because his '%CO_2' rebreathing performance results have no objective benchmark or threshold to be compared against." 2018 WL 5906075, at *7. Therefore, even if Leshner's testing "satisfactorily showed that one mattress performed better (i.e., had a lower %CO_2 reading) on the test than a different mattress, nothing in the record explains how that %CO_2 reading correlates to the real world or an objective standard." *Id.* What's more, "even if some standard or threshold existed that showed what %CO_2 result in the test was too high, that standard could not be used to extrapolate Leshner's results to live infants." *Id.* at *8. Notably, the

court here cited Carleton 1998, the same paper on which Dr. Mannen relied. As Dr. Mannen admitted at the hearing,[261] and as the court in *Rovid* points out, Carleton 1998 stated that these test results could not be equated to expected results in live infants because the testing likely produces "exaggerate[d]" results compared to what a live infant would experience. *Id*.

158. Dr. Mannen's testimony suffers from these same defects.

159. For example, Dr. Mannen concluded that, during the "intended" placement on a Podster, the "trunk" of the newborn-size sagittal device was flexed on average 32° *compared to* a flat mattress, and the "trunk" of an infant-size device flexed on average 36° *compared to* a flat mattress.[262] During the "slouched" placement on a Podster, the "trunk" of the newborn-size sagittal device was flexed on average 47° *compared to* a flat mattress, and the "trunk" of an infant-size device flexed on average 49° *compared to* a flat mattress.[263]

160. Dr. Mannen's testimony teems with these "comparison" conclusions that lack a safety/danger threshold:

a. Trunk Flexion: based on comparing the angles of the four-segment device against a baseline of 0° of a firm, flat mattress.[264]

b. Head/Neck Flexion: Dr. Mannen "calculated the increase in head flexion . . . compared to the normalized firm flat surface measurements."[265]

c. Facilitation of Rolling: Dr. Mannen opined that it is "easier" for an infant to roll on or off a Podster than it is to roll on a firm,

[261] Aug. 7, 2023 Tr. 136:4–22.
[262] CCX-1, p. 35 (Table 1).
[263] CCX-1, p. 35 (Table 1).
[264] *See above*, Proposed Conclusions of Law ¶¶33–40.
[265] *See above*, Proposed Conclusions of Law ¶¶41–56.

flat mattress.[266]

d. Muscle Fatigue: based on the increase in muscle activity infants require on a Podster, compared to that required on a firm, flat mattress.[267]

e. Rebreathing: based on comparisons between the Podster and a firm, flat mattress.[268]

f. I "found significantly increased trunk flexion angle, especially compared to the firm flat crib mattress."[269]

g. In the 2021 Wang study, "We compared between the firm flat crib mattress" and inclined-sleep products.[270]

h. Measurement of neck angle compared to rigid trunk of a CAMI doll.[271]

i. For the rebreathing analysis, "I was relying on the comparison of the crib mattress…."[272]

j. A product with "appropriate airflow" means that "the work of breathing would not increase when the infant breathes into the product," while a product "without appropriate airflow" means that an infant "would require *increased* work to achieve the exchange of air required for respiration."[273]

k. The Podster's concave shape and high sides make it *more likely* that an infant's nose and mouth will come into contact with the Podster's sides, which—*compared to* an infant lying on firm, flat mattress—increases the risk for airflow and rebreathing.[274]

l. With respect to rebreathing, Dr. Mannen's report warns of "breathing in too much CO2."[275] CX-1 at 49–50. But Dr. Mannen admitted that, based on the values from the test she ran, she doesn't know how much CO2 is "too much."[276] Instead, Dr.

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[266] *See above*, Proposed Conclusions of Law ¶¶65–81.
[267] *See above*, Proposed Conclusions of Law ¶¶82–89.
[268] *See above*, Proposed Conclusions of Law ¶¶106–122.
[269] Aug. 7, 2023 Tr. 61:19–22.
[270] Aug. 7, 2023 Tr. 86:11–12.
[271] Aug. 7, 2023 Tr. 114:22–118:1.
[272] Aug. 7, 2023 Tr. 139:2–3.
[273] CCX-1, p. 24 (emphasis added).
[274] CCX-1, pp. 25–26, 28–29 (emphasis added).
[275] CO_2. CCX-1, pp. 27, 49–50; *see also* Aug. 7, 2023 Tr. 131:5–13.
[276] Aug. 7, 2023 Tr. 139:15.

Mannen "used a comparison" and "talk[ed] about the data in comparison to that crib mattress condition."[277]

m. Dr. Mannen refers to Mannen 2022, which (Dr. Mannen says) "established that mesh-like airflow represents a condition where air can flow freely through material."[278] Mannen 2022 "established that a pressure of less than 0.31 inches of water (in H_2O; this is a unit of pressure) . . . was an appropriate threshold to ensure safety."[279] This "threshold" was determined by comparing airflow-test results of crib bumpers, which had apparently been associated with fatalities, and mesh liner products, which—based on data from unpublished research—"are not known to have resulted in fatalities."[280]

n. Both "head/neck and trunk flexion are much *higher* for infants when placed supine in the Leachco Podster products *compared to* a firm, flat crib mattress."[281]

o. Any neck angle above 0° "puts the baby at a *higher* risk for *further* flexion, which *can* be dangerous," that is, creates a "*higher* risk that [a baby] can *more easily* achieve a neck flexion that will influence" breathing.[282]

p. Dr. Mannen's reliance on Lin 2006 to show that a flexed-trunk posture during sitting, "not unlike" an infant's posture in a Podster, results in reduced lung capacity and lower expiratory flow—*compared to* a normal standing posture.[283]

q. The Podster reduces the coordinated movements required for rolling and thus makes it "*easier*" to roll in a Podster *than* on a firm, flat surface.[284]

r. Infants lying prone on a product "like" a Podster experience "*up to 2.5 times more* abdominal muscle activity *compared to* lying on a firm, flat mattress . . . .";[285] this comparison "means that infants are now recruiting muscles that facilitate breathing for

[277] Aug. 7, 2023 Tr. 139:17–19.
[278] CCX-1, p. 25.
[279] CCX-1, p. 25.
[280] CCX-1, Ex. C (Mannen 2022), pp. 215, 221.
[281] CCX-1, p. 38 (emphasis added).
[282] Aug. 7, 2023 Tr. 119:12–22 (emphasis added).
[283] CCX-1, p. 39.
[284] CCX-1, pp. 42–43; *see* Aug. 7, 2023 Tr. 140:3–8 (Dr. Mannen's admitting that she doesn't know how much easier it is to roll in a Podster compared to rolling on a firm, flat surface).
[285] CCX-1, p. 44 (emphasis added) (citing Mannen 2019).

movement as well, meaning these muscles vital to breathing will fatigue *more quickly*, which *can* lead to a dangerous suffocation situation."[286]

s. "'[T]he combination of incline angle and product design requires infants to use significantly more core effort (abdominal strength) to maintain a prone position *compared to* lying on a flat surface.'"[287]

t. "'[I]nfants attempt to maintain a safe prone posture to facilitate breathing, which places an *increased* demand on the core muscles as suggested by the EMG [muscle activity] results.'"[288]

u. Loose bedding is a known suffocation hazard for infants, so if the Leachco Podster pillow facilitates rolling from the pillow onto an unsafe sleep space, an infant is subjected to *increased* risk of death."[289]

v. "[I]f an infant was breathing into" a Podster, the infant would require "*significantly more* work to breathe."[290]

w. "CO_2 increased from 5.6% CO_2 on the crib mattress with a sheet to 13.7% CO_2 on the Leachco Podsters, *an increase of nearly 2.5 times*," and "O_2 inhalation decreased from 19.6% in the crib mattress condition to 17.8% on average in the Leachco Podsters." CCX-1, p. 49. These results, according to Dr. Mannen, show that "if an infant breathes into the Leachco Podster, the O_2 decreases and the CO_2 substantially increases, increasing the risk for hypoxia (not breathing enough oxygen) and breathing in too much CO_2."[291]

x. Dr. Mannen opined that the Podster "[c]auses a flexed head/neck and flexed trunk posture during supine lying, inhibiting normal breathing," but never defined "normal" breathing.[292]

y. Dr. Mannen acknowledged that while there are "head-neck flexion values that introduce significant breathing respiration hazards[,]" no "hard and fast" safety/danger threshold has been

[286] CCX-1, p. 44 (emphasis added) (citing Mannen 2019).
[287] CCX-1, pp. 44 (emphasis added) (quoting Wang 2021).
[288] CCX-1, pp. 45 (emphasis added) (quoting Wang 2021).
[289] CCX-1, p. 46 (emphasis added).
[290] CCX-1, pp. 48–49 (emphasis added).
[291] CCX-1, pp. 49–50 (emphasis added) (citing Expert Testimony of Kr. Katwa).
[292] CCX-1, p. 6.

defined.[293]

z. Dr. Mannen testified that further research is required to improve the accuracy of head-neck flexion results and to determine thresholds for safety.[294]

aa. Dr. Mannen is unaware of a device that can determine a threshold for safety with respect to neck flexion.[295]

bb. Dr. Mannen opined that the Podster "[i]ncreases abdominal fatigue if an infant finds themselves prone in the pillow, *increasing* the risk of suffocation."[296]

cc. Dr. Mannen opined that the Podster "*[n]egatively affects* the ability of an infant to self-rescue from the prone position to a safe breathing position."[297]

dd. Dr. Mannen opined that the Podster "*[n]egatively affects* the ability of an infant to breathe *normally* if they are prone or side-facing in the product.[298]

ee. A product that is "too soft" will deform "too much" and envelop an infant's face if the infant is prone or if her face is pressed against the side of a product.[299]

ff. "[O]ther researchers have reported that changes in trunk posture *can negatively impact* pulmonary and respiratory function."[300]

161. Only once does Dr. Mannen identify something approaching a safety/danger threshold. She stated that medical literature says that a neck-flexion angle of 45° is dangerous.[301] Of course, Dr. Madden is not a medical doctor and has no medical expertise. But even if Dr. Mannen were correct about the threshold, she admitted that

[293] Aug. 7, 2023 Tr. 83:13–21.
[294] Aug. 7, 2023 Tr. 109:5–110:7.
[295] Aug. 7, 2023 Tr. 110:12–15.
[296] CCX-1, p. 6 (emphasis added).
[297] CCX-1, p. 6 (emphasis added).
[298] CCX-1, p. 6 (emphasis added).
[299] CCX-1, p. 21.
[300] CCX-1, p. 39 (emphasis added).
[301] Aug. 7, 2023 Tr. 120:10–11; 121:7–16.

she is unaware of a device that can determine a threshold for safety with respect to neck flexion.[302]

162. Further, this 45° threshold is found in Reiterer 1994, admitted into evidence as RX-34.[303] Notably, Reiterer 1994 measured head/neck flexion by laying the live infants "on a flat surface with the head placed on specially constructed wooden neck boards with slopes of 15°, 30°, and 45°, respectively."[304] Dr. Mannen's neck-flexion measurements were obtained by using a different (non-validated) method: CAMI dolls.[305] And the Commission's medical expert, Dr. Katwa, did not identify a proper way to measure neck flexion.[306]

163. The case in *Rovid* is instructive, once again, with respect to Dr. Mannen's use of terms like "hazardous" or "increased risk" or "negatively affects." In *Rovid*, Lesnher testified, "I define more CO_2 as more hazardous, it's a continuum, from low to high." 2018 WL 5906075, at *8. But as the court pointed out, "[m]any, if not most, substances do not become hazardous until a certain threshold level is reached. Without supporting evidence or qualifying expertise, Leshner cannot merely assert that any amount of CO_2 rebreathing is hazardous." *Id*. Here, Dr. Mannen failed to even offer definitions for these kinds of terms.

164. And, even if Dr. Mannen had identified any thresholds, she still failed to show that any threshold "could . . . be used to extrapolate [her] results to live infants."

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[302] Aug. 7, 2023 Tr. 110:12–15; 119:2–3.
[303] *See* CCX-1 (Mannen Report), p. 66 (citing 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); Aug. 7, 2023 Tr. 152:18–22.
[304] RX-34, p. 002.
[305] CCX-1, pp. 19–20.
[306] Aug. 9, 2023 Tr. 13: 20–22.

Rovid, 2018 WL 5906075, at *8. As noted above, none of the methods she used for her expert testimony has been peer-reviewed and validated. For example:

a. Dr. Mannen did not validate that the neck-flexion measurements she took correspond to how real infants would sit or move in a Podster.[307]

b. Dr. Mannen testified that her head-rotation test is a "valid test to show how an infant's normal interaction with the product influences the risk that [an infant] will come into contact" with the product.[308] But Dr. Mannen admitted that she turned the CAMI dolls' heads for purposes of her test; that she has never seen how an infant normally interacts with the Podster; and that she discusses the "normal" range of motion in her report—but not in a Podster.[309]

c. The Mannen 2023 study used this head-rotation test.[310] In this 2023 study, Dr. Mannen and her team concluded: "While this head rotation test is interesting and the test methodology is simple, a less subjective test with a well-defined threshold for safety related to the risk that an infant's mouth/nose will contact a plush product may be a better option."[311]

165. Similarly problematic are Dr. Mannen's opinions that rely on continencies that Dr. Mannen herself was supposed to determine. For example, Dr. Mannen opines that "*if* an infant breathes into the Leachco Podster, the O_2 decreases and the CO_2 substantially increases, increasing the risk for hypoxia (not breathing enough oxygen) and breathing in too much CO_2."[312] The problem is that Dr. Mannen herself was offered to testify about the alleged dangers in the Podster.[313]

[307] Aug. 7, 2023 Tr. 82:22–83:8.
[308] Aug. 7, 2023 Tr. 128:3–6.
[309] Aug. 7, 2023 Tr. 128:15–129:10.
[310] RX-36, pp. 060–066.
[311] RX-36, p. 065.
[312] CCX-1, pp. 49–50 (citing Expert Testimony of Kr. Katwa).
[313] *See* CCX-1, p. 5 ("I have been retained by the Consumer Product Safety Commission ("CPSC") to evaluate Podster products manufactured by Leachco, Inc. and *assess whether their design creates a risk of injury* for infants.") (emphasis added).

166. The same circular, assume-the-premise defects are found throughout Dr. Mannen's report. Thus, Dr. Mannen claims that the Podster's design "[i]ncreases abdominal fatigue *if* an infant finds themselves prone in the pillow, increasing the risk of suffocation;"[314] that the Podster's design "[n]egatively affects the ability of an infant to breathe normally *if* they are prone or side-facing in the product;"[315] that "the lack of firmness or the presence of extra padding in the sleep surface alters an infant's ability to move which *could* contribute to the increased risk of suffocation *if* an infant struggles to move into a safe breathing position;"'[316] and "*If* an infant becomes fatigued while lying prone on the product before a caregiver recognizes the problem, the infant therefore is at *high* risk for suffocation.")[317]

167. One other example deserves additional comment. Dr. Mannen opines: "'*If* an infant achieves a roll from supine to prone within an inclined sleep product, the limited horizontal space and pliant concave surface *likely* makes rolling prone to supine difficult or impossible.'"[318] As explained above, Dr. Mannen failed to establish that infants will easily roll into a prone position on the Podster. First, Dr. Mannen claimed merely that it is "easier"—but she doesn't know how much easier—for infants to roll in Podster than on firm, flat mattress.[319] Second, Dr. Mannen's "rolling" opinions are not supported by any testing and are all but completely undermined by Kobayashi 2016, which Dr. Mannen cites for support.[320]

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[314] CCX-1, p. 5 (emphasis added).
[315] CCX-1, p. 5 (emphasis added).
[316] CCX-1, p. 44 (emphasis added) (quoting Wang 2021).
[317] CCX-1, p. 46 (emphasis added).
[318] CCX-1, pp. 44–45 (quoting Wang 2021) (emphasis added).
[319] Aug. 7, 2023 Tr. 140:3–8.
[320] *See above*, Proposed Conclusions of Law ¶¶65–81.

168. Thus, while it may be true, for example, that infants can breathe in "too much" CO_2 *in certain situations—e.g.*, situations created by the Podster's design—Dr. Mannen here assumes the existence of these situations rather than proving that these situations will or are likely to occur.

169. Leachco's expert witness Peggy Shibata—whose qualifications Complaint Counsel does not challenge—described the methodological flaws in Dr. Mannen's studies (Mannen 2019 and Mannen 2020, on which Dr. Mannen relied here).[321] The Court finds Ms. Shibata's critique persuasive.

170. Mannen 2019 includes significant redactions.[322] In particular, many of these redactions appear to hide the devices used in testing. Without this information, these tests cannot be repeated. Dr. Mannen herself acknowledged that for testing to be accurate, it must be repeatable.[323]

171. The Court must also consider the potential impact that Dr. Mannen's past and ongoing work for the CPSC has on the independence of her opinions. The CPSC provided around $250,000 for research led by Dr. Mannen when she was an adjunct professor at the University of Arkansas.[324]

172. The CPCS has continued to fund Dr. Mannen's research since then, and the current contract runs through 2024.[325]

[321] RX-1 (Shibata Report), pp. 14–24.
[322] *See* CCX-1, Ex. B (Mannen 2019), pp. 116, 121, 123–25, 128, 169–173.
[323] Aug. 7, 2023 Tr. 78:20–21.
[324] Aug. 7, 2023 Tr. 87:9–20.
[325] Aug. 7, 2023 Tr. 87:21–91:7.

d. Dr. Mannen's testimony about infants in the "slouched" position is excluded for additional reasons

173. All of the conclusions above apply to Dr. Mannen's opinions concerning infants in both the intended and slouched positions.

174. But Dr. Mannen's testimony concerning infants in the slouched position is excludable for three additional reasons:

a. None of the three incidents at issue here involved an infant or newborn in a slouched position.

b. Complaint Counsel has no evidence showing how often, if at all, infants or newborns find themselves in a slouched position.

c. Dr. Mannen has never observed an infant sliding into a slouched position in a Podster.[326]

5. Dr. Katwa's testimony is unhelpful to the trier of fact in this case

175. This Court concludes that Dr. Katwa is qualified to testify about pediatric pulmonology.

176. But, as previously ordered, Dr. Katwa is not qualified to testify about the Podster's design, alleged use of the Podster, and alleged defective marketing by Leachco.[327] Accordingly, his opinions concerning the Podster's design, alleged defects in the Podster, alleged use of the Podster, and allegedly misleading marketing were stricken.[328]

177. Therefore, only Dr. Katwa's testimony related to his area of expertise—pediatric pulmonology—is admitted.

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[326] Aug. 7, 2023 Tr. 126:8–13
[327] Aug. 2, 2023 Order (Dkt. No. 128), pp. 6–7.
[328] *Id.*

178. As noted above, a qualified expert's testimony must be both (1) reliable and (2) relevant.

179. The Court concludes that Dr. Katwa's testimony about pediatric pulmonology is reliable and trustworthy.

180. But the Court concludes that Dr. Katwa's testimony is not relevant to the task at hand. Expert opinion testimony is relevant if the knowledge underlying it has a "valid . . . connection to the pertinent inquiry." *Daubert*, 590 U.S. at 591–92. As Rule 702 requires, it must "assist the trier of fact to understand the evidence or to determine a fact in issue." *Id*. at 591. But "scientific validity [and relevance] for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id*.

181. Dr. Katwa's testimony on the potential dangers has no bearing *in these circumstances*. To be sure, the Court accepts Dr. Katwa's background summary regarding infant physiology, breathing, and sleep,[329] but this information is relevant *only if* other evidence shows that the Podster's design and use create the dangers that Dr. Katwa discusses. That is, while Dr. Katwa has identified "background" information,[330] he acknowledged that the information applies generally to all infants.[331] And Dr. Katwa conceded that his opinions about what can happen to infants depends on infants' position and movement in the Podster.[332]

182. Complaint Counsel may argue that Dr. Katwa's testimony, combined with Dr. Mannen's and Ms. Kish's, proves a defect. Thus, even though Dr. Mannen is not

[329] CCX-3, pp. 5–16.
[330] CCX-3, pp. 5–16.
[331] Aug. 9, 2023 Tr. 8:8–9:3.
[332] Aug. 9, 2023 Tr. 8:4–7.

a doctor or nurse, has no medical or nursing degree, and has no certifications in medicine,[333] she (the argument might go) properly cites Dr. Katwa. For example, Dr. Mannen opined: "if an infant breathes into the Leachco Podster, the O_2 decreases and the CO_2 substantially increases, increasing the risk for hypoxia (not breathing enough oxygen) and breathing in too much CO_2."[334]

183. There are at least two problems with Dr. Mannen's reliance on Dr. Katwa here.

184. First, Dr. Katwa is not a biomechanics or design expert. Therefore, he cannot opine with respect to the possibility or odds of an infant's "rebreathing." And, as explained above, Dr. Mannen provides no evidence to show that the nose/mouth of infants in the *intended* position come into contact with the Podster. Further, while Dr. Mannen found that the nose/mouth region of CAMI dolls can come into contact with the Podster if the CAMI doll is in a slouched position, there is no evidence in this case that any infant has in fact slouched in a Podster.

185. Second, precisely because Dr. Mannen does not provide sufficient evidence to show a design defect in the Podster, Dr. Katwa's testimony on the potential dangers have no bearing *in these circumstances*. As noted above, Dr. Katwa admits that his "background" information[335] applies generally to all infants.[336]

186. Again, the *Rovid* case is informative, as it explains why Dr. Katwa's testimony about general pulmonology fails to demonstrate a defect in the Podster:

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[333] Aug. 7, 2023 Tr. 168:2–12.
[334] CCX-1, pp. 49–50 (citing CCX-3 (Katwa report) pp. 15–17, 20, 23–24, & 30).
[335] CCX-3, pp. 5–16.
[336] *See* Aug., 7, 2023 Tr. 8:8–9:3.

> Plaintiffs argue that even without Leshner, the three medical experts are sufficient to survive summary judgment. While those opinions may be sufficient to show that the mattress contributed to or caused Leanne's death, they are not evidence that a design defect existed. None of the doctors examined the subject mattress or any other mattress and therefore have no basis for concluding anything about the mattress' design, much less concluding that some feature of its design was defective. Charitably, the three doctors opine that the mattress caused Leanne's death. As discussed above, that alone does not give rise to the inference that the mattress was defectively designed. The court has little doubt that any mattress would eventually cause death if the occupant was laying face down and unable to move. Thus, without Leshner's testimony, plaintiffs lack evidence showing a *design* feature of the subject mattress proximately caused Leanne's death.

Rovid, at *16.

187. Because the Court finds that the opinions of Dr. Mannen (*see* above) and Ms. Kish (*see* below) unreliable, unpersuasive, and/or unhelpful to this case, the Court does not consider Dr. Katwa's general background information related to infant breathing—because that general information is unhelpful to the trier of fact in these circumstances.

6. Complaint Counsel failed to show that the Podster's design uniquely encouraged the foreseeable misuse alleged

a. Ms. Kish's testimony

188. The Commission introduced the testimony of Celestine Kish, offered to provide expert testimony on "human factors."[337]

189. Relevant here, Ms. Kish testified that consumers' observations of other consumers' misuse can encourage misuse and that it is foreseeable that consumers will use the Podster in a dangerous manner.

[337] *See* CCX-2 (Kish Report). This Court previously ordered that all claims and evidence concerning Leachco's allegedly defective warnings were stricken. *See* Aug. 2, 2023 Order (Dkt. 128), pp. 3–5.

190. Ms. Kish's opinions are unreliable and must be excluded because they are not based on any methodology, much less a proven methodology, and relatedly because Ms. Kish points to merely anecdotal "evidence." Indeed, Ms. Kish claimed that she didn't need scientific data to support her internet-search opinions.[338] Like Dr. Mannen, Ms. Kish identifies no standard or threshold for determining when social-media influence "pacifiers" become "too" influential or dangerous.

Consumer Influence/Pacifiers

191. Ms. Kish opines that "'people will often use the behavior of others to infer the appropriate action for a given situation.'"[339] Ms. Kish does not provide information to say how often this occurs.[340]

192. Similarly, Ms. Kish opines 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."[341] Again, Ms. Kish does not say how much "more likely" this phenomenon is.[342] Nor does Ms. Kish discuss other factors that could persuade people *not* to speed, jaywalk, etc.[343]

193. Ms. Kish opines that no warnings could make the Podster safe because of "pacifiers."[344] In this context, "pacifiers" are "a form of social influence that can affect consumers' motivation to follow warnings. Pacifiers can come from any influence on

[338] Aug. 8, 2023 Tr. 92:6–8.
[339] CCX-2, p. 34 (¶66) (citation omitted).
[340] Aug. 8, 2023 Tr. 42:11–43:1.
[341] CCX-1, p. 35 (¶67) (citation omitted).
[342] Aug. 8, 2023 Tr. 43:2–5.
[343] Aug. 8, 2023 Tr. 43:6–14.
[344] *See* CCX-2, p. 34; Aug. 8, 2023 Tr. 37:2–4.

a consumer, including observing the way other consumers interact with a product or its warnings."[345]

194. According to Ms. Kish, "[c]ounter-examples can act as pacifiers to decrease compliance in many situations."[346] Ms. Kish testified that people are more prepared to exhibit specific patterns of behavior that they have observed.[347]

195. Ms. Kish states that the internet and social media are "rife" with counter-examples.[348] Ms. Kish does not define "rife."[349]

196. For her expert testimony, Ms. Kish ran her own searches on the internet. For example, Ms. Kish searched Instagram for posts tagged "#leachopodster".[350] This search produced 24 results, 18 of which contained images of infants sleeping in a Podster.[351]

197. Ms. Kish opines that these images show a "significant, alarming pattern" of counter-examples that, she says, "pacify[] dangerous consumer use of the Podster."[352] Ms. Kish does not define "pattern," nor does she say what a "significant, alarming pattern" is.[353]

[345] CCX-2, p. 34 (¶65).
[346] CCX-2, p. 34 (¶66).
[347] Aug. 8, 2023 Tr. 40:7–13; 42:4–7.
[348] CCX-2, p. 42 (¶83).
[349] Aug. 8, 2023 Tr. 43:20–44:7.
[350] CCX-2, p. 42 (¶84).
[351] CCX-2, p. 42 (¶84).
[352] CCX-2, p. 44 (¶86).
[353] Aug. 8, 2023 Tr. 46:10–17.

198. Similarly, Ms. Kish later opines that certain counter-examples are "prevalent throughout the internet."[354] But Ms. Kish does not define "prevalent" and doesn't attempt to quantify the supposed prevalence of these examples.[355]

199. Ms. Kish claims that "[m]any consumers are influenced by what they see other people do on social media," and "social media 'influencers' can have an outsized effect on consumer behavior."[356] But Ms. Kish never quantified how many consumers are so influenced.[357]

200. Ms. Kish does not know how many consumers ran the searches that she ran, and she does not know how many consumers, if any, saw the results identified in her report.[358] Nor does she know how long, if at all, any consumer viewed these results.[359] She didn't study any of these questions, and she doesn't know how influential any of the images she found actually are.[360]

201. Ms. Kish opines that a consumer looking to buy a Podster as an infant-sleep product or who already has a Podster could be persuaded by the images on Instagram.[361] But Ms. Kish does not quantify this presumed influence, and she admits that a consumer also could *not* be influenced by the Instagram images.[362]

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[354] CCX-2, p. 53 (¶102).
[355] Aug. 8, 2023 Tr. 55:18–56:2.
[356] CCX-2, p. 44 (¶86).
[357] Aug. 8, 2023 Tr. 46:18–22.
[358] Aug. 8, 2023 Tr. 44:14–45:12; 47:6–10-22.
[359] Aug. 8, 2023 Tr. 45:13–15; 47:9–11.
[360] Aug. 8, 2023 Tr. 45:7–9; 48:1–3.
[361] CCX-2, p. 45 (¶87).
[362] Aug. 8, 2023 Tr. 48:10–22.

202. Ms. Kish identified another source of purported influence on consumer behavior—an article about the Podster in New York Magazine.[363] Ms. Kish says that a product review in such a publication "could" influence consumer behavior.[364] But she does not identify the extent of this presumed influence.

203. Ms. Kish claims that "New York Magazine is a publication that most consumers would likely view as a credible, neutral reviewer of consumer products."[365] Ms. Kish admitted, however, that she does not know how many consumers would view New York Magazine as a credible, neutral reviewer of consumer products; does not know the circulation of New York Magazine; does not know how many subscribers the magazine has; does not know the demographics of its readers; does not know if New York Magazine regularly reviews consumer products; and does not know if "most consumers" are even aware of New York Magazine.[366]

204. Similarly, Ms. Kish points to a review on Amazon.com,[367] but she does not know, *e.g.*, how many consumers view Amazon.com each day; nor does she know how many consumers decide to buy products based on Amazon reviews; nor does she know, for example, whether motorcycle consumers are more likely to be persuaded by reviews on Amazon.com than dining-room table consumers.[368] Ms. Kish did not look study these types of questions for her report.

[363] CCX-2, pp. 45–46 (¶¶89-90).
[364] CCX-2, p. 46 (¶90).
[365] CCX-2, p. 46 (¶90).
[366] Aug. 8, 2023 Tr. 49:4–50:7.
[367] CCX-2, p. 56 (¶107)
[368] Aug. 8, 2023 Tr. 56:4–22.

205. Ms. Kish also admitted that she gathered no data about how consumers search the internet for product reviews of the Podster or for any product.[369] She didn't study this issue at all.[370]

206. More generally, for all the examples of supposed "influence" in Ms. Kish's report, Ms. Kish did not conduct any surveys or studies to determine whether consumers actually viewed images or product reviews or any of the other examples in the report.[371] Nor did Ms. Kish look for data to how long, if at all, any consumers viewed the examples in her report.[372]

207. Ms. Kish did not identify any methodology to show that the searches she ran for purposes of preparing her expert report correlate with how consumers would search (and be influenced by) the internet.[373]

Foreseeable Misuse

208. Ms. Kish opines that it is foreseeable that consumers will use the Podster for infant sleep, for co-sleeping in an adult bed, on elevated surfaces, and in other infant products, such as cribs.[374]

209. Ms. Kish states that consumers are likely to do "anything" to get infants to fall and stay asleep.[375] Therefore, a caregiver who perceives that an infant sleeps

[369] Aug. 8, 2023 Tr. 50:13–22.
[370] Aug. 8, 2023 Tr. 51:5–6.
[371] Aug. 8, 2023 Tr. 51:7–13.
[372] Aug. 8, 2023 Tr. 51:14–21.
[373] Aug. 8, 2023 Tr. 51:22–53:15.
[374] CCX-2, p. 4.
[375] CCX-2, p. 60 (¶118).

better in an inclined position "may be persuaded" to let the infants sleep in a Podster.[376]

210. According to Ms. Kish, caregivers who are traveling or dealing with "significant" financial hardship "may be more likely" to allow an infant to sleep in a Podster for lack of a crib.[377]

211. Some caregivers, Ms. Kish writes, "may not" appreciate that unsupervised infants can move or roll into a dangerous position because they "many not" be aware of current safe-sleep practices.[378]

212. Ms. Kish further opines that if an infant falls asleep in a Podster, caregivers may intentionally or accidentally fall asleep, relax, or catch up on chores, and leave the infant unattended.[379]

213. Ms. Kish says that for consumers who want to bedshare, the Podster "may be" an attractive option.[380] Ms. Kish did not do any research to support that statement.[381]

214. Ms. Kish also says that Leachco's statements about the Podster "can only contribute to consumers' belief that the Podster's design will make bedsharing and general use safe."[382] Ms. Kish acknowledged, however, that she has no evidence about

[376] CCX-2, p. 60 (¶118).
[377] CCX-2, p. 62 (¶121).
[378] CCX-2, p. 62 (¶122).
[379] CCX-2, p. 61 (¶119).
[380] CCX-2, p. 63 (¶124).
[381] Aug. 8, 2023 Tr. 58:11–17.
[382] CCX-2, p. 63 (¶124).

consumers' beliefs concerning whether the Podster's design will make bedsharing safe.[383]

215. According to Ms. Kish, caregivers are "unlikely" to understand that using the Podster for bedsharing does not eliminate the suffocation risk, and there is no evidence that the Podster's high sides will eliminate the risk of overlay."[384] But Ms. Kish admitted that she had no evidence that consumers believe the Podster's high sides will prevent overlay.[385]

216. Ms. Kish relies on Drago 2021. [386] According to that study, adult beds were associated with 78% or share-sleep fatalities, and the primary "fatality pattern" was overlay and probable overlay.[387] Ms. Kish admitted that this primary fatality pattern involves infants in adult beds *with or without other products.*[388]

217. Ms. Kish states that Leachco's marketing "encourages" consumers to engage in "other activities" while an infant is in a Podster.[389]

218. Ms. Kish also testified that consumers may rely on Leachco's description of the Podster's "high sides," a description that Ms. Kish stated parents may rely on to leave their baby unsupervised because they may believe that the high sides will keep the infant in the product.[390]

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[383] Aug. 8, 2023 Tr. 59:12–20.
[384] CCX-2, p. 64 (¶125).
[385] Aug. 8, 2023 Tr. 60:2–9.
[386] Drago et al., "Infant fatality patterns in shared sleep: keys to intervention strategies?," *Proceedings of the 2021 HFES 65th International Annual Meeting*, 1322-1326, at 1323–25 (2021). *See* CX-2 at p. 60 n.114.
[387] Aug. 8, 2023 Tr. 61:9–14.
[388] *Id*. 61:15–18.
[389] CCX-2, p. 61 (¶119).
[390] Aug. 8, 2023 Tr. 37:5–40:4.

b. Ms. Kish's testimony is unreliable

219. Assuming Ms. Kish is qualified, the Court finds that her testimony is unreliable.

220. According to Ms. Kish, "'[i]t is a well-documented social phenomenon that people are more prepared to exhibit specific patterns of behavior if they observe other people demonstrating that behavior even when that behavior is not necessarily in their best interest.'"[391] As Ms. Kish concedes, for this to occur, people must observe others engaging in the behavior in question.[392]

221. But Ms. Kish failed to use a proven methodology and anything more than anecdotal evidence to support the asserted influence of other people's misuse. Indeed, Ms. Kish admitted that she didn't quantify or conduct any studies or surveys to determine this claimed influence:

> 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 other examples in your report, do you?
>
> A. No, I do not.
>
> …
>
> Q. Nor do you identify any methodology by which you conducted your searches, correct.
>
> A. I do not provide that, correct.[393]

222. Ms. Kish's opinions concerning foreseeable misuses were likewise devoid of studies. For example, in her report, Ms. Kish opined that if a "caregiver wishes to

[391] CCX-2, pp. 34–35 (¶66) (citation omitted).
[392] Aug. 8, 2023 Tr. 40:5–42:10.
[393] Aug. 8, 2023 Tr. 51:9–13; 51:22–52:2.

bedshare with their infant, the Podster may be an attractive option to them,"[394] but at the hearing, Ms. Kish admitted that she did no research to determine whether that opinion was true.[395]

223. Finally, Ms. Kish testified that she does not "quantify the risk."[396] Rather, she "look[s] at it in terms of what is about the product itself that *could* have *potential* hazards."[397]

224. As a result, the Court must exclude Ms. Kish's testimony. *See, e.g.*, *Rovid*, 2018 WL 5906075; *Trademark Properties, Inc. v. A&E Television Networks*, No. 2:06-cv-2195-CWH, 2008 WL 4811461, at *2 (D.S.C. Oct. 28, 2008) (rejecting supplemental expert opinion as unreliable because expert's opinion relied on "article in the New York Times and on information revealed by various internet searches," but was not based on any proven methodology); *Spangler Candy Co. v. Tootsie Roll Indus., LLC*, 372 F.Supp.3d 588, 595–96 (N.D. Ohio 2019) (excluding portion of expert's testimony because opinion was "informed by various blogs and articles he discovered through internet searches conducted in preparation of this case" and because expert "did not verify the underlying data and methodology used to reach the conclusions upon which he relies and quotes"); *Doe v. AE Outfitters Retail Co.*, No. WDQ-14-508, 2015 WL 9255325, at *5 (D. Md. Dec. 17, 2015) (finding inadmissible expert's proffered analysis about foreseeability of invasion of privacy because analysis was based on only "a basic internet search and 'common knowledge'").

[394] CCX-2, p. 60 (¶124).
[395] Aug. 8, 2023 Tr. 58:11–16. *See also above*, Proposed Conclusions of Law ¶215.
[396] Aug. 8, 2023 Tr. 29:9.
[397] Aug. 8, 2023 Tr. 29:13–15 (emphasis added).

c. Impossible and Imaginary Standard—"Perfect Parental Supervision"

225. Finally, even if Ms. Kish had properly supported her testimony it is ultimately unreliable and unpersuasive because the crux of her testimony is fatally undermined by the Commission itself (and others).

226. The crux of Ms. Kish's expert testimony is that "[f]rom a human factors engineering perspective, the Podster presents a hazard that cannot be mitigated by warnings and depends on perfect parental supervision, which is not possible."[398]

227. But she was forced to acknowledge that CPSC itself, like American Academy of Pediatrics and the National Institutes for Health—all entities that Ms. Kish says are reliable organizations which provide reliable information—doesn't require perfect supervision.[399]

228. Ms. Kish and Dr. Katwa acknowledge that newborns and young infants can and do fall asleep often and in various places.[400] The CPSC itself, the American Academy of Pediatrics, and the National Institutes for Health recognize this fact, too.[401]

229. Indeed, Ms. Kish, Dr. Katwa, the CPSC, the AAP, and the NIH all recognize that infants can fall asleep in *unsafe*-sleep environments.[402]

230. The safe-sleep recommendation of the CPSC, the AAP, and the NIH, is *when an infant falls asleep in an unsafe-sleep environment*, a caregiver should move the infant to a safe-sleep environment as soon as is safe and practical.[403]

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[398] CCX-2, p. 5.
[399] Aug. 8, 2023 Tr. 79:14–83:18.
[400] *See* Aug. 8, 2023 Tr. 91:21 (Kish); Aug. 9, 2023 Tr. 14:6–15 (Katwa).
[401] *See* RX-2, p. 004; RX-3, pp. 003, 006; RX-37, p. 010.
[402] Aug. 8, 2023 Tr. 83:8–11; Aug. 9, 2023 Tr. 14:6–15.
[403] *See* RX-2, p. 004; RX-3, pp. 003, 006; RX-37, p. 010.

231. Therefore, Ms. Kish acknowledged that CPSC itself, the AAP, and the NIH don't require perfect supervision.[404]

7. Miscellaneous considerations

232. Complaint Counsel asked Leachco's founder and current Vice President whether Leachco had tested the Podster for things like airflow and firmness before marketing the product.[405] But the Commission points to no statute or regulation that requires manufacturers like Leachco to test for airflow, firmness, etc. Leachco uses a third party to conduct required tests.[406] Further, the Commission failed to identify any thresholds through its experts that a manufacturer could rely on to test for airflow, etc. Accordingly, the lack of such testing has no bearing on whether the Podster is a "substantial product hazard" under the CPSA.

233. The Commission applies its standards haphazardly and arbitrarily. Here, it claims that the Podster is a sleep product, even though it falls outside of the inclined-sleeper rule (as confirmed by Ms. Kish's testimony) because the Podster—as the Commission admits—was never marketed for sleep. But in other circumstances, the Commission concludes that a highchair is a sleep product because it was marketed for sleep.[407]

234. Ms. Kish states that consumers wishing to leave their infant unsupervised "could use safer, regulated infant products such as play yards, bassinets, and cribs,

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[404] Aug. 8, 2023 Tr. 83:15–18.
[405] *See* Aug. 8, 2023 Tr. 141:8–13.
[406] *See* JX-18.
[407] https://www.cpsc.gov/Newsroom/News-Releases/2023/CPSC-Warns-Consumers-to-Immediately-Stop-Using-iCraves-Infant-High-Chairs-Due-to-Suffocation-Entrapment-and-Fall-Hazards-Failure-to-Meet-Federal-Safety-Standards

which are subject to mandatory standards regarding sleep surfaces, instead of the Podster."[408] Ms. Kish further acknowledged consumers interested in bed sharing would likely turn to products that can easily be used in bed such as baby boxes or in bed sleepers if they remain available. Alternatively, consumers may use adult side pillows or other forms of bedding to bed share with their infants.[409] These points further support the Court's conclusion that the tragic deaths at issue here and the risk of harm to infants are created because of, among other things, unsafe-sleep environments and not any defect in the Podster's design.

B. Even if the Commission had proven that the Podster had a design defect, Complaint Counsel failed to prove that any defect created a substantial risk of injury to the public

1. Substantial risk of injury

235. A "substantial product hazard" is "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2).

236. Therefore, the Commission must prove that "*because of*" the "pattern of defect, the number of defective products distributed in commerce, the severity of risk, or otherwise," the Podster "*creates* a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2) (emphasis added). *See* July 6, 2023 Order (Dkt. No. 99) p. 3 ("Complaint Counsel is still required to demonstrate the alleged defect's creation of that risk.");

[408] CCX-2, p. 5 (¶4).
[409] Aug. 8, 2023 Tr. 64:4–14. *See also* RX-34 (PSA 0598.21), p. 16.

id., p. 8 (Complaint Counsel "must . . . demonstrate that that injury is the result of the alleged defect.").

237. "[T]he ordinary meaning of 'because of'" incorporates the standard of but-for causation, *Bostock v. Clayton County*, 140 S.Ct. 1731, 1739 (2020), and the ordinary meaning of "create" is "to bring into existence" or "to cause to be or to produce by fiat or by mental, moral, or legal action" or "to bring about by a course of action or behavior," WEBSTER'S THIRD NEW INT'L DICTIONARY 532 (1993).

238. The Commission failed to demonstrate by a preponderance of the evidence that any infant has been injured by the Podster when consumers use the product for its intended purpose and when its warnings and instructions are heeded.

2. The "pattern of defect, the number of defective products distributed in commerce, the severity of risk, or otherwise"

239. The number of products distributed in commerce—180,000 Podsters—and the severity of the risk—death—satisfy that part of 15 U.S.C. § 2064(a)(2). *See id*. § 2052(a)(14) (defining "risk of injury" as "a risk of death, personal injury, or serious or frequent illness.").

3. A substantial product hazard is a product defect which *creates* a substantial risk of injury to the public

240. The statute defines "risk of injury" as "a risk of death, personal injury, or serious or frequent illness." *Id.* § 2052(a)(14).

241. The term "substantial" modifies "risk of injury," a phrase defined in the CPSA as "a risk of death, personal injury, or serious or frequent illness." 15 U.S.C. § 2064(a)(14).

242. But because the "risk of injury" includes substantial or significant effects—including, most obviously, death—the phrase "substantial" cannot itself mean substantial or significant injury.

243. "Substantial" modifies the "risk of injury" and thus means the level of the risk—not the seriousness of the injury. *See Johnson v. United States*, 576 U.S. 591, 603 (2015); *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153–54 (2010); *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014).

244. The Commission's proposed reading of 15 U.S.C. § 2064(a)(14) is implausible because it would define "substantial product hazard" as a *product defect that creates a risk of substantial/significant injury* and thus read "substantial" out of the statute. *See United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933 (2009) (explaining that statutes must be read "in a manner that gives effect to all of their provisions").

245. Further, the Commission's proposed reading of the statute would require the ban of all infant products, in which death and serious injury are *possible outcomes* of the products' use.[410]

246. Therefore, the Court concludes that "substantial risk of injury" means a significantly high probability of injury.[411]

[410] *See* RX-20 (CPSC Reports, *Nursery Product-Related Injuries and Deaths Among Children under Age Five*, 2009–2022).
[411] *See* Leachco's Mtn. for Summary Decision, pp. 37–45.

4. Even assuming a defect exists, the Commission failed to prove by a preponderance of the evidence that any defect in the Podster creates a substantial risk of injury to the public

247. The Commission failed to demonstrate by a preponderance of the evidence that any alleged defect of the Podster ***creates*** a "substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2).

a. The Commission failed to prove that the Podster caused the tragic death in the Alabama Incident

248. As stated above, there are factual discrepancies related to the Alabama Incident.[412]

249. There is also evidence that the infant suffered from bronchiolitis.[413]

250. And, as explained above, the Commission failed to prove that the Podster created a substantial risk of injury to the public.

251. Here, the Commission offered no first-hand accounts of the incident.

252. The autopsy report did not reveal an obvious cause of death.[414] It was noted that the infant's death was "consistent with" an "asphyxia type" death.[415] Ultimately, according to the Medical Examiner's office, the cause of death was "best listed as complications of asphyxia with the manner of death being accident."[416]

253. Evidence shows, unfortunately, that accidents like the Alabama Incident occur regularly.

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[412] *See above*, Proposed Findings of Fact ¶26.
[413] JX-06, pp. 19, 25.
[414] JX-06, p. 19.
[415] JX-06, p. 19.
[416] JX-06, p. 19.

254. Approximately 3500 infants death each year are classified as SIDS.[417]

255. And the Commission's own studies show that infants are injured and die in all manner of infant products—often because of the same circumstances that apparently occurred here: co-sleeping, extra bedding, caregiver's lack of supervision, etc.

256. For all of these reasons, the Court concludes that the Commission failed to establish that the Podster, or any defect in the Podster's design, was the cause of the infant's death.

b. The Commission failed to prove that the Podster caused the tragic death in the Texas Incident.

257. As stated above, there are factual discrepancies related to the Texas Incident.[418]

258. Apparently, the infant had been making gasping sounds sometimes and was scheduled for a doctor's appointment two days after she passed away.[419]

259. And, as explained above, the Commission failed to prove that the Podster created a substantial risk of injury to the public.

260. Here, the Commission offered no first-hand accounts of the incident.

261. The medical-examiner's report stated that "[p]ositional asphyxia due to co-sleeping in an unsafe sleep environment cannot be excluded as contributory given the circumstances at the time of death and the finding of anterior lividity at the time of autopsy."[420] The Medical Examiner concluded that the cause and manner of death

[417] RX-37, p. 001.
[418] *See above*, Proposed Findings of Fact ¶¶31–33.
[419] JX-08, pp. 4, 22.
[420] JX-08, p. 13.

were "undetermined."[421] The Medical Examiner therefore classified the cause of death as sudden unexpected death in infancy (SUDI), which applies after a "thorough investigation, medical history review, autopsy, and appropriate laboratory testing fail to identify a specific cause of death."[422] The Medical Examiner noted that positional asphyxia due to "co-sleeping in an unsafe sleep environment" could not be excluded "as contributory."[423] Ultimately, the manner of death was certified as "undetermined."[424]

262. Evidence shows, unfortunately, that accidents like the Texas Incident occur regularly.

263. For all of these reasons, the Court concludes that the Commission failed to establish that the Podster, or any defect in the Podster's design, was the cause of the infant's death.

c. The Commission failed to prove that the Podster caused the tragic death in the Virginia Incident.

264. As stated above, there are factual discrepancies related to the Virginia Incident.[425]

265. The autopsy reports notes that the Virginia infant had chronic bronchitis.[426] A week before she passed away, she was taken to a doctor for congestion.[427]

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[421] JX-08, p. 13.
[422] JX-08, p. 13.
[423] JX-08, p. 13.
[424] JX-08, p. 13.
[425] *See above*, Proposed Findings of Fact ¶48.
[426] Ex. JX-12A(1), p. 5.
[427] Ex. JX-12A(1), p. 9.

The infant also had a possible ear infection.[428] The infant was taking Albuterol.[429] The infant had been sick for several days.[430] A week before the incident, the infant had been taken to the pediatrician because she was "very congested;" she was prescribed respiratory treatments for breathing/wheezing.[431] Two days before the incident, the infant's mother called 911 because the infant was having trouble breathing.[432] The infant was "very congested" and had vomited mucus and had a "difficult time" breathing.[433]

266. And, as explained above, the Commission failed to prove that the Podster created a substantial risk of injury to the public.

267. Here, the Commission offered no first-hand accounts of the incident.

268. According to the autopsy report for the Virginia Incident, the cause of death was "[s]udden unexpected infant death with unsafe bedding and positioning," and the manner of death was "[u]ndetermined."[434]

269. Evidence shows, unfortunately, that accidents like the Virginia Incident occur regularly.

270. For all of these reasons, the Court concludes that the Commission failed to establish that the Podster, or any defect in the Podster's design, was the cause of the infant's death.

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[428] Ex. JX-12A(1), p. 8.
[429] Ex. JX-12A(1), p. 8.
[430] Ex. JX-10, p. 11.
[431] Ex. JX-10, p. 6.
[432] Ex. JX-10, p. 11.
[433] Ex. JX-10, p. 11.
[434] Ex. JX-12A(1), pp. 3, 5.

271. As discussed above, the Court concludes that (among other reasons) the failure to follow recommended safe-sleep guidelines—and not the Podster—here creates whatever risk of infant death exists here.

d. The Commission's expert testimony failed to prove that the Podster's (assumed) defects create a substantial risk of injury to the public

272. For the reasons set forth above, the Court finds the CPSC's proffered expert testimony unreliable and/or or irrelevant.

273. Accordingly, the Court does not conclude that the CPSC's proffered expert testimony supports the Commission's claim that the Podster's alleged design defect creates a substantial risk of injury to the public.

e. Infant deaths during sleep are caused overwhelmingly by failures to follow safe-sleep guidelines

274. Approximately 3500 infants death each year are classified as SIDS.[435]

275. As the American Academy of Pediatrics observes, "[a]fter a substantial decline in sleep-related deaths in the 1990s, the overall death rate attributable to sleep-related infant deaths has remained stagnant since 2000 . . .."[436]

276. And the Commission's own studies show that infants are injured and die in all manner of infant products, *including many products that the CPSC itself promotes for safe sleep*: cribs and bassinets.[437] And these deaths are caused mainly because of a lack of following safe-sleep recommendations. For example, the CPSC reported 137

[435] RX-37, p. 001.
[436] RX-37, p. 001.
[437] RX-20 (CPSC Reports, *Nursery Product-Related Injuries and Deaths Among Children under Age Five*, 2009–2022), p. 152 (Table 4).

infant deaths were associated with cribs.[438] And, according to the CPSC, about 73 percent of these deaths "were associated with a cluttered sleep environment (the presence of extra bedding in the crib, such as pillows, blankets, and/or comforters, among others) that led to asphyxiation of the infant."[439] The same is true for infant deaths in bassinets.[440] Deaths from co-sleeping were also reported.[441]

277. Complaint Counsel's expert witnesses acknowledged these unsafe-sleep deaths.[442]

278. Leachco's expert witness Ms. Shibata testified that the risk here is caused, not by the Podster's design, but by failure to follow safe-sleep recommendations.[443]

279. The Court concludes that the evidence is additional proof that the Podster's design did not cause the deaths at issue here, nor does the Podster's design create a substantial risk of injury to the public.

f. The evidence here

280. Finally, the Court's conclusion would be the same even if the Commission had proven that the Podster did in fact cause the three tragic deaths at issue in this case.

281. Leachco has sold approximately 180,000 Podsters.

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[438] RX-20, p. 152 (Table 4).
[439] RX-20, pp. 152–53.
[440] RX-20, p. 153.
[441] RX-20, p. 153.
[442] Aug. 8, 2023 Tr. 83:1-18 (Kish); Aug. 9, 2023 Tr. 48:3–14 (Katwa). The Commission offered evidence that two people associated with Leachco had improperly used the Podster for sleep. *See* CCX-42, CCX-43. The Court finds that this evidence demonstrates that human behavior is the key determinant here.
[443] RX-1 (Shibata Report), pp. 9–10.

282. The Commission alleges three deaths associated with the Podster but no other injuries.

283. Therefore, assuming each Podster is used only a single time, the chances of death or injury would be 0.0017% (3 / 180,000)—less than two-one-thousandths of a percent.

284. Ms. Kish testified that it's "likely" that each Podster is used multiple times.

285. Assuming each Podster is used only ten times, the rate of injury or death would be the injury rate (3 / 1,800,000) would be 0.0000017, or 0.00017 percent.

286. The Court, of course, does not want to minimize any deaths. But the law requires the Commission to prove that a defect creates a "substantial" risk of injury to the public. Even assuming that the three deaths here were caused by the Podster, the Court cannot conclude that the Podster's design creates that "substantial" risk.

III. ADDITIONAL EVIDENTIARY RULINGS

287. The Court admitted into evidence JX-06, JX-07, JX-08, JX-09, JX-10, and JX-11, which are copies of the CPSC's IDIs concerning the three incidents alleged to be associated with the Podster. JX-06 and JX-07 are, respectively, the unredacted and redacted copies of the "Alabama IDI." JX-08 and JX-09 are, respectively, the unredacted and redacted copies of the "Texas IDI." JX-10 and JX-11 are, respectively, the unredacted and redacted copies of the "Virginia IDI."

288. Each IDI includes hearsay documents.

289. Some of these documents are public records under Fed. R. Evid. 803(8). Public records are an exception to the hearsay rule, and the Court considers those documents for the truth of the matters asserted therein.

290. But, as noted above, the IDIs contain materially conflicting information.[444] At the hearing, the Court admitted the IDIs into evidence, stating that they were "generally admissible."[445] The Court noted, however, "to the extent that they are comprised of reliable hearsay, they could be argued to be admissible subject to the objections that you have raised to that type of evidence[;] [a]nd to the extent that they are not hearsay in the sense that these were documents that prompted some action by the investigators and are not offered for the truth contained in those documents, they would be admissible on that basis as well."[446]

291. Complaint Counsel offered no first-hand witnesses of the three incidents at issues here. And Complaint Counsel offered no evidence to resolve the discrepancies in the IDIs. Most importantly, Complaint Counsel did not prove:

> a. Whether the infant from the Alabama Incident (after being left unattended with a bottle in his mouth) was found (i) face up or (ii) face down;[447]
>
> b. Whether the infant from the Texas Incident (after being breastfed by her mother) (i) was placed in the Podster or (ii) was kept with her mother as she fell asleep breastfeeding;[448]
>
> c. Whether, in the Virginia Incident, the infant's face was (i) in contact with the side of the Podster or (ii) not in contact.[449]

292. These discrepancies are crucial here, because the Commission alleges that the Podster's design makes it "easier" for infants to roll on or off the Podster into dangerous positions or situations. Without resolving these key disputes, the

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[444] *See above*, Proposed Findings of Fact ¶¶26, 31–33, 48.
[445] Aug. 7, 2023 Tr. 203:15–16.
[446] Aug. 8, 2023 Tr. 9: 3–11.
[447] *See above*, Proposed Findings of Fact ¶26.
[448] *See above*, Proposed Findings of Fact ¶¶ 31–33.
[449] *See above*, Proposed Findings of Fact ¶¶48.

Commission has failed to offer more than contradictory hearsay evidence. The Court cannot resolve these disputes on such a thin basis.

CONCLUSION

293. Leachco's Podster does not contain a product defect under the CPSA.

294. Leachco's Podster does not create a risk of injury to the public under the CPSA.

295. Leachco's Podster does not create a substantial risk of injury to the public under the CPSA.

296. The Commission has failed to demonstrate that the Podster is a "substantial product hazard" under 15 U.S.C. § 2064(a), (c)-(d).

297. Therefore, the Commission cannot order Respondent to take remedial action.

On these findings of fact and conclusions of law and on the entire record in this case, I recommend dismissal.

* * *

A proposed order is attached.

DATED: September 29, 2023.

Respectfully submitted,

s/ *Oliver J. Dunford*

FRANK D. GARRISON
Indiana Bar No. 34024-49
Pacific Legal Foundation
3100 Clarendon Boulevard, Suite 1000
Arlington, VA 22201
Telephone: 202.888.6881
Fax: 916.419.7747
FGarrison@pacificlegal.org

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

Counsel for Respondent Leachco, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2023, the foregoing was served upon all parties and participants of record as follows:

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

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

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

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

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

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

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

[PROPOSED] ORDER

This matter came before the Court for a hearing held August 7–10, 2023. Upon consideration of the evidence presented at the hearing, it is hereby:

ORDERED, that Leachco's Podster, as a matter of law, does not present a "substantial product hazard" under the Consumer Product Safety Act, as amended, 15 U.S.C. § 2051 *et seq*.; and further

ORDERED, that Complaint Counsel's Complaint be and hereby is **DISMISSED**; and further

ORDERED, that this **ORDER**, along with the accompanying Memorandum Opinion, shall constitute the Initial Decision and Order in accordance with the provisions of 16 C.F.R. §§ 1025.25; and further

ORDERED, that a copy of this Order and accompanying Memorandum Opinion shall be entered on the docket and proceedings before the Presiding Officer are terminated.

Dated: _____

_____
Hon. Michael G. Young
Administrative Law Judge