No. 22-1

Consumer Product Safety Commission

IN THE MATTER OF LEACHCO, INC.

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

RESPONDENT LEACHCO'S ANSWERING BRIEF

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INTRODUCTION

Respondent **LEACHCO, INC.**, pursuant to 16 C.F.R. § 1025.53(c), submits this **ANSWERING BRIEF** in response to Complaint Counsel's Appellate Brief. Complaint Counsel failed to prove that Leachco's Podster is a "substantial product hazard" under the Consumer Product Safety Act. Specifically, as the Presiding Officer correctly held, Complaint Counsel failed to prove that the Podster presents a (1) product defect (2) that creates (3) a substantial risk of injury to the public. The Initial Decision should be affirmed.

* * *

Jamie Leach and her husband Clyde started Leachco out of their home in Ada, Oklahoma, 35 years ago.[1] Its first product pre-dates the company: a safety restraint that Jamie fashioned from her purse strap after her then seven-month-old son almost slipped out of a restaurant high-chair. Within a few days, Jamie designed what became known as the "Wiggle Wrap." People took notice, Jamie and Clyde launched the business, and Leachco developed a variety of products for families to care for their children—an American success story. Jamie, a registered nurse, mother, and now grandmother, still designs all Leachco's products; she has over 40 patents and scores of trademarks.[2] Leachco now employs around 30 workers, including Jamie and Clyde's three adult children.[3] Jamie and Clyde see Leachco as their American Dream: Through hard work, innovation, sacrifice, and perseverance, they built a successful small business in their hometown.

[1] JX-51, Joint Stipulations, ¶¶1, 8.
[2] JX-51, Joint Stipulations, ¶6.
[3] JX-51, Joint Stipulations, ¶¶2, 8.

One product Leachco sells is an infant lounger called the Podster. Since 2009, Leachco has sold over 180,000 Podsters. During this time, Podsters have been used millions of times, providing families with a useful product that enhances their lives.

Yet Complaint Counsel seeks to ban the Podster. It alleges one claim under the Consumer Product Safety Act (CPSA): that the Podster presents a "substantial product hazard," defined 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." 15 U.S.C. § 2064(a)(2). That claim has no merit whatsoever.

First, the Podster is not a defective product. The term "product defect" is not defined by the CPSA. And under the traditional tools of statutory construction—which the Commission is bound to apply—the ordinary and common-law meaning of the statute controls: A product defect is a manufacturing, warning, or design defect. As the Initial Decision cogently explained, under this construction of the statute, the Podster is not defectively designed—it is safe for its intended use, and Complaint Counsel fails to show that there is a safer infant lounger design that would outweigh any alleged dangers posed by the Podster.

That should be the end of this case. But rather than confront the actual statutory text Complaint Counsel is charged with enforcing, it seeks to rely on the Commission's nonbinding regulations, asserting that its arbitrary and standardless factors should override the statute's terms. Under this view, the Podster is defective because "it is foreseeable" that consumers *may* misuse it, and that misuse *could* lead to imagined circumstances that *might* create some

undefined risk. But even under this speculative reasoning, Complaint Counsel failed to meet its burden. Complaint Counsel's experts offer nothing more than flawed, non-peer-reviewed methodologies, and speculative predictions. They provide zero evidence that the Podster has a design defect that created a substantial risk of injury to the public.

Second, assuming a defect exists, Complaint Counsel failed to prove that any alleged defect "*create[d]* a substantial risk of injury to the public." § 2064(a)(2) (emphasis added). Rather, as the evidence shows, the alleged risk of injury asserted by Complaint Counsel is present in every product because the risk is created not by any product, but *by unsafe-sleep environments*.

Third, contrary to the express terms of the CPSA, Complaint Counsel erroneously contends that "a substantial *risk* of injury to the public" means "a risk of substantial *injury*." Thus, under Complaint Counsel's view, the Commission should pretend that § 2064(a)(2) does not require a showing of substantial *risk*, but *any* risk of a substantial *injury*. But the CPSA's plain text defines "risk of injury" as a "a risk of death, personal injury, or serious or frequent illness." § 2052(a)(14). Thus, the "risk of injury"—most obviously, death—is by definition substantial, and the word "substantial" in § 2064(a)(2) must therefore modify the "risk" (of injury) and not "injury." Complaint Counsel no doubt feels compelled to alter the statutory language to make this argument cover the lack of evidence of *defect* or *risk*. But under a proper interpretation of the CPSA, even assuming—contrary to the evidence—that the Podster was the cause of any injuries alleged, there have been only three injuries out of more than 180,000 Podsters, which have been used millions of times. And "the risk of injury from use of the Podsters appears to be vanishingly small—even if one

assumes that the Podster was a proximate cause of death in all three incidents (a conclusion not supported by the available evidence)."[4] This is far from a "substantial risk of injury to the public."

Fourth, if Complaint Counsel's extra-textual interpretations are correct, then the CPSA violates the Major Questions Doctrine, the Nondelegation Doctrine, and Leachco's due process rights. Congress did not sanction the Commission to create an entire regime of federalized products liability through the word "defect." Nor did Congress authorize the Commission to ban all products that create *any* risk of injury. Yet that is exactly what Complaint Counsel asserts here. The Commission should reject this attempt to rewrite the statute in a way that would have such enormous political and economic ramifications for both American businesses and consumers. But if Congress did sanction the Commission to create what amounts to an "industrial code" for consumer products through regulation, then the statute violates the nondelegation doctrine. And maybe worse still, Complaint Counsel's reliance on the Commission's nonbinding regulations amounts to a violation of Leachco's due process rights. No small business (nor any business for that matter) can reliably conform their products to the Commission's regulations, which contain multitudes of factors that the agency *may*, or *may not*, apply—after the fact—to hale people into internal adjudications, and which can even be used to criminally prosecute unwary citizens.

Ultimately, Complaint Counsel's evidence shows—at most—that three infants tragically died because of unsafe sleep practices. The Initial Decision should be affirmed.

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[4] Initial Decision 59.

STATEMENT OF THE CASE[5]

A. Leachco: Jamie and Clyde's American Dream

Respondent Leachco is an Oklahoma corporation founded in 1988 by Jamie Leach and Clyde Leach in Ada, Oklahoma.[6] Leachco currently employs approximately 30 people and manufactures, distributes, and offers for sale more than 90 products for infants, children, and adults.[7] Jamie Leach still designs all Leachco's products.[8]

B. The Podster

The Podster—developed and patented in 2008—is just one of the hundreds of products that Leachco has designed and manufactured for families and caregivers.[9] Leachco first offered the Podster for sale in 2009 and has sold approximately 180,000 of them.[10] As Leachco explains, the Podster "provides a warm and cozy caress for infants. The deeply contoured sides help keep the baby in place while the unique sling center expands with infant's weight. … [It] is specifically designed to help with daytime care of awake infants for the countless times each day when parents and caregivers need to free up their hands for the activities of daily life. The Podster provides a safe, secure spot to place an infant on its back as the parent or caregiver supervises hands-free, able to prepare a meal, pay bills, check email, give a hand to siblings, and many other daily tasks."[11]

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[5] Pursuant to the Administrative Procedure Act, the exclusive record in this appeal consists of "[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding[.]" 5 U.S.C. § 556(e).
[6] JX-51, Joint Stipulations, ¶¶1, 8.
[7] JX-51, Joint Stipulations, ¶¶2, 8.
[8] JX-51, Joint Stipulations, ¶6.
[9] Tr. 2, 112:2–3.
[10] JX-51, Joint Stipulations, ¶¶12–13.
[11] Initial Decision 2 (citing JX-51, Joint Stipulations, ¶¶15–16).

The Podster. *See* https://leachco.com/products/podster (last visited Oct. 14, 2024).

Podsters have likely been used "millions" if not "tens of millions" of times.[12] It is designed and marketed as an infant lounger.[13] It is not and has never been advertised by Leachco as a sleep product.[14] Accordingly, the Podster is not an inclined sleeper for infants, *i.e.*, a product "with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old." 15 U.S.C. § 2057d(b). Congress banned inclined sleepers for infants. *See id.* § 2057d(a). Because the Podster is not an inclined sleeper for infants, it is not covered by that ban.[15] The Commission has also never adopted a consumer product safety rule to regulate or ban the Podster or any infant lounger. *See* 15 U.S.C. § 2052(a)(6) (defining consumer product safety rule). In contrast, the Commission has adopted consumer product safety rules to ban or regulate other

[12] Initial Decision 59; *see also* Tr. 2, 68:9–11 (Kish).
[13] JX-51, Joint Stipulations, ¶9.
[14] JX-51, Joint Stipulations, ¶18.
[15] Tr. 2, 36:1–9 (Kish).

infant products, including cribs,[16] high chairs,[17] infant-bouncer seats,[18] car seats,[19] and inclined infant sleepers.[20] Thus, Complaint Counsel does not allege that the Podster violates a consumer product safety rule.

Further, as Complaint Counsel acknowledges, and the Presiding Officer found,[21] Leachco provides express warnings and instructions about the proper use of the Podster. Complaint Counsel concedes that the Podster (1) contains warnings that it should not be used for sleep and that adult supervision is always required;[22] (2) contains warnings that the product should only be used on the floor—not in another product, such as a crib, or on a bed, table, playpen, counter, or any elevated surface;[23] (3) contains warnings that infants should not be placed prone or on their side in the product;[24] (4) 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.[25] Complaint Counsel further acknowledges that the Podster contains warnings and instructions that use of the product in contravention of these warnings could result in serious injury or death.[26]

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[16] 16 C.F.R. pt. 1219, Safety Standard for Full-Size Baby Cribs; *id*. pt. 1220, Safety Standard for Non-Full-Size Baby Cribs.
[17] 16 C.F.R. pt. 1231, Safety Standard for High Chairs.
[18] 16 C.F.R. pt. 1229, Safety Standard for Infant Bouncer Seats.
[19] 16 C.F.R. pt. 1225, Safety Standard for Hand-Held Infants Carriers.
[20] *See* Safety Standard for Infant Sleep Products, 86 Fed. Reg. 33,022 (June 23, 2021). Pursuant to the Safe Sleep for Babies Act of 2021, P.L. 117-126, "inclined sleepers for infants" became banned hazardous products (effective Nov. 12, 2022) under the Consumer Product Safety Act. 15 U.S.C. § 2057. An "inclined sleeper for infants" is defined as a product "with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old." *Id*. § 2057d(b).
[21] Initial Decision 3.
[22] JX-51, Joint Stipulations, ¶19.
[23] JX-51, Joint Stipulations, ¶20.
[24] JX-51, Joint Stipulations, ¶21.
[25] JX-51, Joint Stipulations, ¶22.
[26] JX-51, Joint Stipulations, ¶23.

Complaint Counsel does not allege that Leachco's warnings are defective.[27] Rather, as discussed below, Complaint Counsel alleges that the Podster is defective "despite" Leachco's warnings and instructions.

C. Unsafe-Sleep Environments

Complaint Counsel asserts that the Podster presents a "substantial product hazard." 15 U.S.C. § 2064(a)(2). It claims that the Podster's inclined, compliant, soft, and insufficiently permeable design creates an alleged risk. It asserts that the Podster is defective based on conjectural hazards such as airflow obstruction, lack of firmness, facilitation of movement on and off the product, facilitation of rolling, positional asphyxia, and encouragement of bedsharing.[28]

Complaint Counsel relies almost entirely on expert testimony.[29] It also points to three tragic deaths—isolated instances resulting from unsafe-sleep environments that were completely unrelated to any product. The Commission itself recognizes young infants (and parents) may fall asleep in environments that don't meet safe-sleep recommendations.[30] Indeed, the Commission *anticipates* that babies will fall asleep in all kinds of products—including products that the Commission promotes for safe sleep. The Commission therefore recommends:

a. "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."[31]

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

[27] Initial Decision 39–40.
[28] *See* Compl., ¶¶48–52.
[29] Initial Decision 6.
[30] Tr. 2, 91:21 (Kish); Tr. 3, 14:6–15 (Katwa).
[31] RX-02, p. 004.

sitting or carrying device, move them to their regular sleep space as soon as possible."[32]

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."[33]

The Commission even recommends how (as safely as possible) to co-sleep:

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."[34]

The American Academy of Pediatrics offers similar recommendations:

"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."[35]

Despite these recommendations, approximately 3,500 infant deaths a year are classified as SIDS—Sudden Infant Death Syndrome.[36] These deaths occur in cribs, adult beds, car seats, infant-bouncer seats, and all manner of sleep environments.[37]

The Commission has noted that most infant deaths in nursery products occurred in a cluttered sleep space, when soft bedding was added to the cribs, playpens/play yards or bassinets/cradles—products that the Commission itself

[32] RX-03, p. 003.
[33] RX-03, p. 006.
[34] RX-03, p. 007.
[35] RX-37, p. 010 (emphasis added) (footnote citations omitted).
[36] Tr. 3, 47:6–8 (Katwa).
[37] *See* RX-37, p. 001; Tr. 3, 47:6–8 (Katwa).

recommends for safe sleep.[38] For example, according to the CPSC report, between 2017 and 2019, 137 deaths were associated with cribs and mattresses[39]—products that are recommended for safe sleep and subject to CPSC consumer product safety rules.[40] And almost three-fourths 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)."[41]

Complaint Counsel's non-expert evidence—most of which is contradictory hearsay—shows, if anything, that the three tragic deaths here were caused by these unsafe-sleep practices: cluttered sleep environments, extra bedding, and—in this case—leaving a baby unsupervised with a bottle in his mouth.[42] But Complaint Counsel has no evidence, and produced none at the hearing, of any injuries that were caused by the Podster or any other product. Unsafe-sleep *practices*—not any product—led to the heartbreaking incidents.

D. Complaint Counsel's Allegations

Nonetheless, Complaint Counsel alleges that the Podster is a "substantial product hazard" under the Consumer Product Safety Act, 15 U.S.C. § 2064(a)(2). The complaint acknowledges that the Podster "is not and has never been advertised by [Leachco] as a sleep product" and that the Podster comes with express warnings against using the Podster for sleep, placing the Podster in a

[38] *See* RX-20, pp. 151–54.
[39] RX-20, p. 152.
[40] 16 C.F.R. pt. 1219, Safety Standard for Full-Size Baby Cribs; *id*. pt. 1220, Safety Standard for Non-Full-Size Baby Cribs; *id.* pt. 1241, Safety Standards for Crib Mattresses.
[41] RX-20, p. 152–53.
[42] JX-07, Alabama IDI, p. 2.

crib or on any elevated surface, bedsharing, using the Podster with infants over 16 pounds or infants who can roll over.[43]

Yet, Complaint Counsel's complaint alleges, *despite* these warnings, "it is foreseeable" that consumers "may" misuse the Podster. For example, the complaint asserts that caregivers "may trust that the products are safe places to leave infants" or "may" leave a sleeping infant in a Podster; consumers "who are traveling or who are dealing with significant financial hardship may be more likely to" allow an infant to sleep in a Podster; and unsupervised infants "can" roll or move off the Podster.[44] The complaint asserts that the design of the Podster is defective because, *e.g.*, it allegedly "facilitates" an infant's movement on the Podster, which purportedly "enhance[es]" some undefined and indeterminate "risk that the infant's nose and mouth will be obstructed" by the Podster or by another object such as soft bedding.[45] The complaint also claims the Podster is defective because it "may be attractive to caregivers who wish to bedshare with an infant."[46]

The complaint further alleges that the Podster poses a "substantial risk of injury" because of the (allegedly) foreseeable misuses.[47] This "foreseeable misuse" standard arises not from the text of the CPSA (15 U.S.C. § 2064(a)(2)) but from a non-binding, interpretative regulation (16 C.F.R. § 1115.4).[48] According to the law, a "substantial product hazard" is "a product defect which (because of the pattern of defect, the number of defective products distributed

[43] Compl., ¶¶14–19.
[44] Compl., ¶¶20(a), (b), (d), 21.
[45] Compl., ¶¶27–28.
[46] Compl., ¶32; *see also id*. ¶33.
[47] Compl., ¶¶38–41.
[48] Compl., ¶¶44–46; *see also* CPSC Supp. Resp. to Leachco RFA, No. 275 (admitting that 16 C.F.R. § 1115.4 is an interpretive rule).

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).[49] But the complaint alleges that the Podster "contain[s] defects because it is foreseeable" that consumers will misuse it and because, *e.g.*, the Podster's design "may lead to it being used for bedsharing, which can facilitate an infant's rolling off the product …."[50]

The complaint asks for a determination that the Podster presents a "substantial product hazard" and that public notice is required to adequately protect the public.[51] Finally, the complaint seeks an order compelling Leachco to conduct a recall, refund purchasers, and pay damages to third parties who incur recall-related costs.[52]

E. Procedural History

1. Following extensive discovery, the Commission held a hearing August 7–10, 2023, at its Bethesda, Maryland offices. The Commission appointed Administrative Law Judge Michael G. Young to conduct the hearing.[53] The Commission's Complaint Counsel called six witnesses, including three expert witnesses—Dr. Erin Mannen; the Commission's 34-year employee, Senior Engineering Psychologist Celestine Kish; and Dr. Umakanth Katwa. Complaint Counsel also called another Commission employee, CPSC staff investigator Elizabeth Phillips; a former CPSC compliance officer Christopher Nguyen; and Jamie Leach, Leachco's Vice President and Chief of Product

[49] *See* Compl., ¶44.
[50] Compl., ¶¶50, 50(e).
[51] Compl., Relief Sought ¶¶A, B.
[52] Compl., Relief Sought ¶C.
[53] Dkt. 18, p. 1.

Development. Leachco called one expert witness, Dr. Peggy Shibata. The parties filed post-hearing briefs on September 29, 2023.[54]

2. On July 3, 2024, the Presiding Officer issued his Initial Decision rejecting Complaint Counsel's sole claim that the Podster presents a substantial product hazard under the CPSA.[55]

a. The Presiding Officer began with a systematic analysis of the evidence presented at the hearing.[56] This analysis included, among other things, a review of the testimony and evidence provided by Dr. Mannen,[57] Ms. Kish,[58] Dr. Katwa,[59] and Dr. Shibata.[60] The Presiding Officer also analyzed the three In-Depth Investigation Reports (IDIs) offered by Complaint Counsel to support its claim.[61]

b. After reciting his factual findings, the Presiding Officer held that under the CPSA, Complaint Counsel failed to prove by a preponderance of the evidence that the Podster is a substantial product hazard.[62] As a way of background only, he identified the Commission's mission, as established by the CPSA, as "protect[ing] the public against unreasonable risks of injury associated with consumer products."[63]

He then described the legal framework—discussing 15 U.S.C. § 2064(a)(2) and 16 C.F.R. § 1115.4—that guides whether and when the Commission may

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[54] Dkt. 143, 144.
[55] Dkt. 148, Initial Decision.
[56] Initial Decision 2–36.
[57] *Id.* at 6–14.
[58] *Id.* at 15–24.
[59] *Id.* at 26–31.
[60] *Id.* at 31–36.
[61] *See id.* at 3, 10, 12, 14–15, 23, 26, 31–33.
[62] *Id.* at 65.
[63] *Id.* at 37 (citing 15 U.S.C. § 2051(b)(1)).

recall a product that presents a substantial product hazard.[64] Applying that framework, the Presiding Officer held that Complaint Counsel failed to prove its case: *i.e.*, he held that the Podster is not defectively designed under either the CPSA or the Commission's regulations.

First, the Presiding Officer held, Complaint Counsel failed to put forth evidence that the Podster is dangerous for its intended use or that there is a safter alternative design Leachco could have adopted for infant loungers like the Podster.[65] Second, the Presiding Officer held, Complaint Counsel failed to meet its burden under 16 C.F.R. § 1115.4. Despite noting Complaint Counsel's failure to carry its burden under the statute's ordinary meaning might be enough to "refute the existence of a design defect in the Podster,"[66] the Presiding Officer nonetheless meticulously analyzed the evidence under the defect factors laid out in § 1115.4.[67]

Applying those factors, the Presiding Officer held that Complaint Counsel failed to prove (and disclaimed any obligation to prove) that the Podster lacks utility for consumers;[68] failed to prove that infants are vulnerable to a risk of injury because of the Podster's design;[69] and failed to prove the Podster presents an obvious risk of danger to infants when considering the product's warnings and the role of consumer misuse.[70] Moreover, none of § 1115.4's other enumerated factors—products liability law, the Commission's own case law, nor

[64] *Id*. at 38–39.
[65] *Id*. at 40–43.
[66] *Id*. at 43.
[67] *Id*. at 43–56.
[68] *Id*. at 44–46.
[69] *Id*. at 46–49.
[70] *Id*. at 49–52.

the Commission's expertise—support Complaint Counsel's theory that the Podster is defective because of its alleged potential for misuse.[71]

c. The Presiding Officer then held, in the alternative—assuming the Podster has a design defect—that Complaint Counsel also failed to show the Podster's design creates a substantial risk of injury to the public.[72] At the outset, the Presiding Officer noted that although Complaint Counsel may not need to prove that the Podster is the "but for" cause of any injuries or deaths, it must show that a "substantial risk of injury in fact exists, and that the Podster's design created the risk."[73] According to the Presiding Officer, Complaint Counsel failed to do so. First, the Presiding Officer found that the data and evidence disprove Complaint Counsel's assertion the Podster creates a substantial risk of injury to the public.[74] Indeed, as the Initial Decision found, data shows any potential risk of injury associated with the Podster (if any exists at all) "appears to be vanishingly small."[75] Second, Complaint Counsel's evidence concerning the three incidents and its experts' speculation did not support a conclusion that the Podster presents a defect which creates a substantial risk of injury to the public.[76] Instead, Complaint Counsel's evidence, including its expert witness, showed that the risk of injury—if any—is associated with dangerous sleep environments, not any particular product.[77]

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[71] *Id*. at 52–56.
[72] *Id*. at 56–64.
[73] *Id*. at 56.
[74] *Id*. at 58–59.
[75] *Id*. at 59.
[76] *Id*. at 60–62.
[77] *Id*.

3. Shortly after the Presiding Officer issued his Initial Decision, Complaint Counsel filed its intent to appeal, and Leachco filed its intent to cross-appeal.[78]

STANDARD OF REVIEW AND BURDEN OF PROOF

In the adjudicative hearing, Complaint Counsel had the burden to prove, by a preponderance of the evidence, that the Podster was a "substantial product hazard" under 15 U.S.C. § 2064(a)(2). *See In re 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.); CPSC Br. 5.

According to the Administrative Procedure Act, the Commission conducts a de novo review of the Initial Decision. *Zen Magnets*, 2017 WL 11672449, at *6. According to the Commission's rules, it "shall consider the record as a whole or such parts of the record as are cited or as may be necessary to resolve the issues presented and, in addition, shall, to the extent necessary or desirable, exercise all the powers which it could have exercised if it had made the Initial Decision." 16 C.F.R. § 1025.55(a). Further, the Commission "shall adopt, modify, or set aside the findings, conclusions, and order contained in the Initial Decision, and shall include in its Final Decision a statement of the reasons for its action and any concurring or dissenting opinions." *Id.* § 1025.55(b). Nonetheless, the Commission cannot ignore the Presiding Officer's Initial Decision, which is part of the record on appeal. 5 U.S.C. § 557(c). Further, if the Commission departs

[78] Dkt. 149; Dkt. 151.

from the Presiding Officer's findings, the Commission's decision must reflect "attentive consideration" to the Initial Decision. *La. Pub. Serv. Comm'n v. FERC*, 522 F.3d 378, 395 (D.C. Cir. 2008) (citing *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 853 (D.C. Cir. 1970)). This consideration "may be found if the agency decision reflects an awareness of the [Presiding Officer's] findings and gives reasons for reaching a different conclusion with respect to those findings." *Simon v. Simmons Foods, Inc.*, 49 F.3d 386, 390 (8th Cir. 1995); *see also* 16 C.F.R. § 1025.55(b) (requiring the Commission to "include … a statement of the reasons for its action and any concurring or dissenting opinions"). *See Zen Magnets*, 2017 WL 11672449, at *6.

ARGUMENT[79]

I. THE PRESIDING OFFICER CORRECTLY CONCLUDED THAT COMPLAINT COUNSEL FAILED TO PROVE A SUBSTANTIAL PRODUCT HAZARD.

The Commission alleges that the Podster is a "substantial product hazard," which is defined 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." 15 U.S.C. § 2064(a)(2). Accordingly, Complaint Counsel had the burden to 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*, 2017 WL 11672449, at *8. The Presiding Officer correctly ruled that Complaint Counsel utterly failed to carry its burden.

In response, Complaint Counsel asserts (CPSC Br. 6–22) that the Presiding Officer erroneously interpreted § 2064(a)(2) and imposed additional

[79] Leachco incorporates its Motion for Summary Decision (Dkt. No. 91) and Post-Hearing Brief (Dkt. No. 144).

burdens on Complaint Counsel. As explained below, this argument fails. Indeed, it is Complaint Counsel that misreads the Consumer Product Safety Act in the hopes of excusing its failure to present even a modicum of evidence to support its allegation that the Podster's design was a "product defect" that created a substantial risk of injury to the public. Complaint Counsel's failure to prove its case—not any error by the Presiding Officer—is the reason Leachco prevailed below.

A. The CPSA's text controls the analysis for determining whether a consumer product presents a "substantial product hazard."

The Commission must apply the traditional tools of statutory construction to determine the best meaning of the CPSA; the agency's own view of the statute receives no deference. *See Loper Bright Enter. v. Raimondo*, 144 S.Ct. 2244, 2268 (2024). First and foremost, if the text's ordinary meaning is clear, it controls. *Sebelius v. Cloer*, 569 U.S. 369, 376 (2013). "Interpreters should not be required to divine arcane nuances or to discover hidden meanings." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 69 (2012). This is because "only the words on the page constitute the law adopted by Congress and approved by the President." *Bostock v. Clayton Cnty.*, 140 S.Ct. 1731, 1738 (2020); *see id.* ("If judges could add to, remodel, update, or detract from old statutory terms inspired only by extratextual sources and our own imaginations, we would risk amending statutes outside the legislative process reserved for the people's representatives.").

The CPSA defines "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." 15 U.S.C. § 2064(a)(2). Under the

CPSA's ordinary meaning, the Commission thus must prove, by a preponderance of the evidence, that (1) the "product" has a "defect" which ... (2) *creates* a "substantial risk of injury to the public." *Id.* What creates—*i.e.*, what causes—that "substantial risk of injury" can be shown (if a defect is established) by "the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise …." *Id.*; *In re Matter of Dye and Dye*, CPSC Dkt. 88-1, 1989 WL 435534, at *5 (CPSC July 17, 1991); *Zen Magnets*, 2017 WL 11672449, at *8.

Complaint Counsel failed to meet its burden under this statutory standard, and the Presiding Officer's Initial Decision should be affirmed.

B. Complaint Counsel failed to prove that the Podster has a product defect.[80]

1. Complaint Counsel alleged a design defect.

As just noted, the CPSA 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." 15 U.S.C. § 2064(a)(2). But the CPSA otherwise leaves terms undefined, and courts therefore look to the common law; and the "'common practice of consulting dictionary definitions to clarify [the] ordinary meaning'" of undefined terms, and the Commission's regulation (16 C.F.R. § 1115.4). *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)); *see also BP Am. Prod. Co. v. Burton*, 549 U.S.

[80] Leachco made similar arguments as here in its Motion for Summary Decision at 23–32. Those arguments are incorporated here by reference.

84, 91 (2006) (holding that undefined statutory terms "are generally interpreted in accordance with their ordinary meaning").

"At a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function." 16 C.F.R. § 1115.4.[81] *See Zen Magnets*, 2017 WL 11672449, at *8; Initial Decision 40 (citing *Defect*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/defect (last updated June 23, 2024) (A "defect" is "an imperfection or abnormality that impairs quality, function, or utility: SHORTCOMING, FLAW."). Further, according to the definitive legal dictionary and the common law, a "product defect" means "[a]n imperfection in a product that has a [1] manufacturing defect or [2] design defect or [3] 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) (same); *see Zen Magnets*, 2017 WL 11672449, at *8 (same).

Here, Complaint Counsel alleged only a design defect. Initial Decision 40; Compl., ¶¶48–52; CPSC Br. 4–5. 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); *see also* Initial Decision 40 (A "design defect" is an "imperfection occurring when the seller or distributor could have reduced or

[81] Leachco continues to object that 16 C.F.R. §§ 1115.4, 1115.12, and related regulations are merely interpretative—and, therefore, non-binding—regulations. Leachco here preserves this objection but, in the alternative, also offers its argument, namely, that Leachco prevails even if these regulations are applied.

avoided a foreseeable risk of harm by adopting a reasonable alternative design, and when, as a result of not using the alternative, the product or property is not reasonably safe.") (quoting *Black's Law Dictionary*).[82]

2. Complaint Counsel failed to prove a design defect.

As the Presiding Officer concluded, Complaint Counsel's "proof problems" on the question of design defect "begin ... at the root." Initial Decision 40. First, Complaint Counsel claims "the 'fault, flaw, or irregularity' that allegedly 'impairs [the] quality, function, or utility' of the Podsters is that they are not a flat, firm surface, inclined no more than 10 degrees and approved by the CPSC for infant sleep." *Id*. (alteration in original). But, as Complaint Counsel admits, the Podster was never designed or marketed for sleep. *See id*. 41 (citing Compl., ¶¶13–14). That admission dooms Complaint Counsel's argument because, as its own expert admitted, the Podster is not subject to the Commission's ban of inclined sleepers (or its ban of infant pillows). Tr. 2, 36:1–9 (Kish). Therefore, Complaint Counsel failed to prove that *the Podster*—a product designed for awake infants under constant adult supervision—has a design defect. Initial Decision 41–43.

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[82] Any objection to Leachco's reliance on the common law is misplaced. When "Congress uses terms that have accumulated settled meaning under the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms." *Neder v. United States*, 527 U.S. 1, 21 (1999) (cleaned up). There is no indication in the CPSA that Congress intended to deviate from settled, common-law understandings. *Cf. Zepik v. Tidewater Midwest, Inc.*, 856 F.2d 936, 942 (7th Cir. 1988) ("For our purposes, it is enough to observe that given the CPSA's structure and legislative history no plausible federal standard could deviate so radically from established concepts of causation in tort ... as to authorize suits under section 23 for reporting violations."). Therefore, because the CPSA "uses a common-law term, without defining it," the CPSA "adopts its common-law meaning." Scalia, *supra*, 320; *see also id*. ("The age-old principle is that words undefined in a statute are to be interpreted and applied according to their common law meanings.").

3. Complaint Counsel's expert witnesses do not support the allegation that the Podster has a design defect.

In its brief (32–61), Complaint Counsel simply regurgitates the testimony of its expert witnesses. In doing so, Complaint Counsel sidesteps its experts' lack of objective benchmarks or validated methods, ignores the damning concessions its experts made during cross-examination, and misleads the Commission by omitting critical portions of the expert reports themselves.

The Commission must consider Federal Rule of Evidence 702, which requires that a proffered witness be "qualified as an expert by knowledge, skill, experience, training, or education."[83] Further, even if a witness is qualified, her opinion may be admitted and considered *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.

Fed. R. Evid. 702. In sum, a proposed expert witness must be qualified, the testimony must help the trier of fact, and the testimony must be reliable. *See United States v. Frazier*, 387 F.3d 1244, 1261 (11th Cir. 2004) ("One may be considered an expert but still offer unreliable testimony. … [U]nder Rule 702, the reliability criterion remains a discrete, independent, and important requirement for admissibility."). This gatekeeping function requires more than

[83] *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.").

simply "'taking the expert's word for it.'" Fed. R. Evid. 702 advisory committee's note (2000 amends.).

a. Dr. Mannen's testimony is unreliable.

In its attempt to establish a design defect, Complaint Counsel relied on the expert testimony of Erin Mannen, Ph.D., a biomechanical engineer. *See* CCX-1 (Mannen Report). But her testimony showed, at most, that the Podster is both (1) similar to a different class of products—inclined sleepers—and also (2) distinct from yet another separate class of products—firm, flat mattresses. *See* CCX-1 (Mannen Report). She failed to establish that *the Podster* is defectively designed (or, as explained below, that any defect created a substantial risk of injury to the public); her testimony consisted entirely of *comparisons* among various types of products. And the flaws in her opinions are manifold—flaws that Complaint Counsel ignored when it repeated her unfounded conclusions.[84] CPSC Br. 32–61. As the Presiding Officer observed, Dr. Mannen herself "conceded limitations in some of the testing methods and devices she used." Initial Decision 11.

Two primary flaws exist. First, Dr. Mannen's testimony failed (with one exception that supports Leachco's case) to identify any objective benchmarks or thresholds by which to identify at what point the Podster's design becomes dangerous or defective such that it creates a substantial risk of injury to the public. Second, ***none*** of the methods Dr. Mannen employed here has been peer-reviewed,[85] Tr. 1, 83:22–85:4, 113:12–17, and ***none*** of those has been validated,

[84] In its Cross-Appeal, Leachco argues that the Presiding Officer erred by not striking Dr. Mannen's testimony in its entirety because of its flawed methodology, lack of objective thresholds, and unreliability. *See* Initial Decision 57–58. Regardless, Dr. Mannen's testimony fails to support the Commission's allegations.

[85] *See* Reference Manual on Scientific Evidence (Fed. Jud. Ctr. 3d ed. 2011) 44 ("Peer review works superbly to separate valid science from nonsense ….").

i.e., shown to accurately reflect live infants in a Podster, *id*. 78:8–13, 82:12–83:8, 107:8–110:7, 113:18–114:9, 166:21–167:21.[86] In short, Dr. Mannen used non-peer-reviewed and non-validated methods to provide merely comparative measurements without identifying objective danger thresholds. *See also* Initial Decision 40–41. Her speculative conclusions are therefore unreliable.

b. Dr. Mannen failed to identify objective benchmarks.

Dr. Mannen summarized her six opinions at CCX-1, pp. 5–6, but neither there nor elsewhere in her report, did she identify any benchmarks or thresholds to determine how and when, if at all, infants might be subjected to a significant risk of injury:

1. Dr. Mannen claims that the Podster's design "[c]auses a flexed head/neck and flexed trunk posture during supine lying, inhibiting normal breathing," CCX-1, p. 6 (footnote omitted), but she never defines "normal" breathing, never states how much flexion is required to inhibit "normal" breathing, and never identifies at what point "normal" breathing is inhibited.
2. Although Dr. Mannen claims that the Podster's design "[f]acilitates some types of rolling on or off of the product, introducing concerning suffocation-related risks for the infant," CCX-1, p. 6, she never says how much the design "facilitates" "some" types of rolling, never defines how "concerning" the alleged risks are, and never identifies at what point the

[86] *Cf. Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591–92 (1993) ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."); *see id.* at 590 n.9 ("In a case involving scientific evidence, evidentiary reliability will be based upon scientific validity.").

"facilitation" of "some" types of rolling becomes concerning—*i.e.*, at what point this presents a substantial risk of injury to the public.

3. Although Dr. Mannen opines that the Podster's design "[i]ncreases abdominal fatigue if an infant finds themselves [sic] prone in the pillow, increasing the risk of suffocation," CCX-1, p. 6, she never states how much abdominal fatigue is "increased" and never defines the "increasing risk" of suffocation or at what point the "increase" in abdominal fatigue presents a risk of injury (suffocation) to the public.
4. Although Dr. Mannen claims that the Podster's design "[n]egatively affects the ability of an infant to self-rescue from the prone position to a safe breathing position," CCX-1, p. 6, she never says how much the design negatively affects the ability of an infant to self-rescue.
5. Although Dr. Mannen opines that the Podster's design "[p]ermits an infant in a supine position to move its face into the sides of the Podster where its nose and mouth are obstructed," CCX-1, p. 6, she never identifies how likely such a move is "permitted."
6. Although Dr. Mannen asserts 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," CCX-1, p. 6, she again fails to define "normally," and she fails to say how much the design (allegedly) negatively affects an infant's ability to breath "normally."

Lacking any thresholds (with one exception, discussed next, that supports Leachco), Dr. Mannen's opinions are based on nothing more than compared measurements on a Podster against measurements of a control—usually a firm, flat mattress. For example, Dr. Mannen asserts that a Podster causes "more"

trunk flexion than does a mattress and that an infant (if her mouth and nose are occluded) will breathe "more" CO_2 from a Podster than from a mattress. CCX-1, pp. 34–35, 49–51. Even if accurate and validated, these measurements are irrelevant—because Dr. Mannen never identifies the point at which "trunk flexion" will become dangerous, *i.e.*, at what point "trunk flexion" poses a substantial risk of injury. In another instance, Dr. Mannen claims that the Podster allows infants to "rebreathe[]" "too much" CO_2. CCX-1, p. 27. But she admitted that she has no idea how much is "too" much. Tr. 1, 139:5–19.

As a result, Dr. Mannen's opinions are completely unreliable. *See, e.g.*, *Rovid v. Graco Children's Prod. Inc.*, No. 17-CV-01506-PJH, 2018 WL 5906075, at *7 (N.D. Cal. Nov. 9, 2018) (excluding expert testimony because: the "results do not support [the expert's] conclusions because his … performance results have *no objective benchmark or threshold to be compared against*") (emphasis added); *Smith v. Cangieter*, 462 F.3d 920, 924 (8th Cir. 2006) (holding, in automobile products-liability action that qualified mechanical engineering expert witness displayed too great an "analytical gap" between fact that a part-time four-wheel drive system *could* under *some* conditions experience *some* slippage, and his opinion that the system was therefore unsafe at highway speeds and required a more adequate warning, since *the expert did not know at what speeds the loss occurred*).

The lone exception concerns neck flexion. Here, Dr. Mannen states that the medical "literature" shows that a neck-flexion angle of 45 degrees is dangerous. Tr. 1, 120:10–11. But she also conceded that she is not aware of any device that can accurately measure neck flexion. *Id.* 110:12–15; 119:2–3. So, for

the only danger threshold she identified in her entire report, she admitted that she can't accurately measure for it.

Complaint Counsel tries to support Dr. Mannen's speculations with testimony from its medical expert Umakanth Katwa, M.B.B.S., M.D. *See* CPSC Br. 32–61. But Dr. Katwa admitted that his testimony was limited to the general physiology of infant breathing in all products and circumstances. *See* Tr. 3, 8:8–9:3; CCX-3, pp. 5–16. Because Dr. Mannen's testimony fails to identify objective thresholds and—as discussed below—because Dr. Mannen's methodologies are hopelessly flawed, Complaint Counsel has failed to demonstrate any defect that creates a risk to infants. And, therefore, Dr. Katwa's general testimony about infant breathing is irrelevant to the facts of this case. *See Daubert*, 509 U.S. at 591–92 (holding that expert opinion testimony is not relevant unless the knowledge underlying it has a "valid ... connection to the pertinent inquiry").

c. Dr. Mannen's methodologies have never been peer-reviewed or validated.

To determine if an expert's methodology is reliable, courts consider, among other factors, (1) whether the methodology can be and has been tested, (2) whether the theory or technique has been subjected to peer review, (3) the known or potential rate of error of the methodology employed, and (4) whether the methodology is generally accepted. *Daubert*, 509 U.S. at 593–94. Importantly, as the Supreme Court explained, "conclusions and methodology are not entirely distinct from one another," and where "opinion evidence ... is connected to existing data only by the *ipse dixit* of the expert," a court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The threshold question concerning proffered expert testimony is "whether the

reasoning or methodology underlying the testimony is scientifically valid and … whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Even a "qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method." *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999).

None of Dr. Mannen's methodologies employed for her expert testimony here have been peer-reviewed or validated. Tr. 1, 78:8–13, 82:12–83:8, 83:22−85:4, 107:8–110:7, 113:12–114:9, 166:21–167:21. Among other things:

Dr. Mannen used crash-test dummies, called "CAMI" dolls—designed for crash tests—to measure "neck flexion," which she claims can be dangerous. To support her use of CAMI dolls for measuring neck flexion, Dr. Mannen cited a 1974 report prepared for the U.S. Department of Transportation, CCX-1, p. 19, but she admitted that she didn't even know whether this report said *anything* about measuring neck angles with CAMI dolls, Tr. 1, 113:8–17. She knows of no peer-reviewed study confirming the use of CAMI dolls to accurately measure live-infant neck angles. Tr. 1, 113:8–17. Dr. Mannen did not include any validation in her expert testimony showing that neck-angle measurements using CAMI dolls correlate with actual infants, and she cited to no peer-reviewed studies that have validated this method of testing infant or newborn neck angles. Tr. 1, 113:18–114:4. Accordingly, Dr. Mannen's expert report did not validate the results she took of the CAMI dolls to show that they correspond to how an infant's neck would actually flex in a Podster. Tr. 1, 114:5–9.

Dr. Mannen also used crash-test dummies to measure "head rotation" in an attempt to support her opinion 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's lying on a firm, flat mattress—supposedly increases the risk for airflow and rebreathing. CCX-1, pp. 25–26, 28–30. But she admitted that she does not know how close to a product a baby's face needs to be before an airflow/rebreathing danger arises. Tr. 1, 123:9–124:2. Further, Dr. Mannen herself placed the CAMI doll in a Podster and rotated the doll's head. Tr. 1, 121:21–122:12, 128:7–10. But she never observed a live infant rotate her head in a Podster, and she doesn't know what the "normal" range of motion should be in a Podster. Tr. 1, 127:16–19, 128:11–129:10. Dr. Mannen used this head-rotation method in her 2023 CPSC-sponsored study. RX-36, pp. 060–066; Tr. 1, 129:11–18. And, in this study, Dr. Mannen and her team admitted: "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." RX-36, p. 065. Not surprisingly, then, nowhere does Dr. Mannen suggest that this test methodology has been peer-reviewed or validated to accurately represent how live infants would or would not move in a Podster (or anywhere else). Therefore, once again, Dr. Mannen employed a non-peer-reviewed and non-validated method but did not identify or test against a safety threshold.

Further, and importantly, when the crash-test dummies were placed in the "intended" position, they all passed Dr. Mannen's test; *i.e.*, the nose/mouth "region" of the dummy's face did not come into contact with the Podster's sides. Tr. 1, 122:13–22. And, as Dr. Katwa testified, if an infant's nose and mouth are not obstructed, there is *no risk* of rebreathing. Tr. 3, 41:1−4. Thus, Dr. Mannen

established zero risk of harm there. When the dummies were placed (by Dr. Mannen) in the "slouched" position, and the dummies' heads were rotated (by Dr. Mannen) 90 degrees, there was some contact between the nose/mouth "region" of a dummy's face and the Podster's sides. CCX-1, p. 53. But Dr. Mannen failed to consider, much less establish, that the "nose/mouth region" of a crash-test dummy accurately represents a live infant. Further, Complaint Counsel presented no evidence that any newborn or infant has ever been in a slouched position. Therefore, because Dr. Mannen's testimony here is neither relevant nor reliable, *Daubert*, 509 U.S. at 592–93, the evidence presented by Complaint Counsel shows zero risk of harm. Dr. Mannen also placed a crash-test dummy in a prone position in the Podster and purported to measure how much head rotation was required to free the nose/mouth region from the Podster. CCX-1, pp. 30−31. Dr. Mannen claimed to find that, to free its nose-mouth region, a crash-test dummy must rotate its head more in a Podster than on a mattress. CCX-1, pp. 55−56. Again, she identified no standard.

Dr. Mannen opines that the Podster makes it "easier" for an infant to roll than on a firm, flat mattress—but she has no idea how much easier, nor does she know how much "ease" is allowed before it becomes dangerous. Tr. 1, 140:3–8.

Again, Dr. Mannen claims that the Podster allows infants to "rebreathe[]" "too much" CO_2. CCX-1, p. 27. But she admitted that she has no idea how much is "too" much. Tr. 1, 139:5–19. Similarly, she testified that for a "rebreathing" risk to exist, a product must retain or pool CO_2. Tr. 1, 133:17–19. But she never tested how much CO_2 a Podster could retain or pool. Tr. 1, 134:1–5. And her testing methods are wholly unreliable and non-validated. She tested each

Podster only a single time with a doll (and tubing through its "nostrils") placed only in a prone position. CCX-1, p. 28; Tr. 1, 134:16–22, 135:1–3. But Complaint Counsel presented no reliable evidence that a baby has ever been found in a prone position.[87] And Dr. Mannen did not perform any tests on live infants, and she did not validate her test results for live infants. Tr. 1, 111:19–21, 135:15–20. Instead, she pointed to Mannen 2019, which ran certain tests on live infants, CCX-1, Ex. B, but Mannen 2019 found *no oxygen-saturation problems* for supine-positioned infants in an inclined-sleep product. Tr. 1, 111:15–18.

During the hearing, Dr. Mannen made a critical omission that is a fair representation of the lack of standards and reliable methodologies throughout her expert report. She stated that her *five*-plane sagittal device—which she said was an improvement over the *four*-plane device she used for her expert report here—is "progressing toward becoming a valid measurement tool to estimate body position." Tr. 1, 107:8–108:16. Perhaps so. But the "courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *see also Edwards v. Safety-Kleen Corp.*, 61 F.Supp.2d 1354, 1360 (S.D. Fla. 1999) ("[T]he literature and hypotheses put forward by [the expert] show a possibility of future general acceptance, providing that future testing can confirm [his] theory. Until that point in time, however, the theory is not scientifically reliable and will therefore be excluded at the trial of this matter.") (citing *Daubert*, 509 U.S. at 590 (as part of its "gatekeeping" responsibilities, the court must rule out "subjective belief or unsupported speculation")).

[87] The only potential evidence of a baby in a prone position (JX-07, Alabama IDI) is contradictory at best. According to documents in the IDI, it "is unclear what position the boy was placed"—his back, front, or side—on the lounger, and it's not clear in what position the baby was found; he may have been face-down or on his back. *Id*. at 2.

Dr. Mannen also relied on studies and methods other than her own—but those studies and methods are similarly flawed. For example, she relied on Carleton 1998's testing model (RX-28). But Carleton 1998 states expressly 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*." RX-28, p. 004 (emphasis added); *see* Tr. 1, 136:4–22 (Mannen). Dr. Mannen did not account for this probable exaggeration. Carleton 1998 also cautioned that "it would *not* be appropriate to *speculate* on the role that rebreathing might have played in any specific case, based solely upon these results." RX-28, p. 005 (emphasis added); *see* Tr. 1, 137:1–12. Yet that is precisely what Dr. Mannen has done here.

Dr. Mannen also relied on Maltese & Leshner 2019 (RX-32) but ignored that paper's admitted limitations: "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 facial anthropometry been examined; both of these factors may influence the interaction between the face and the sample." RX-32, pp. 006–007 (emphasis added). That paper further cautioned that "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*." RX-32, p. 007 (emphasis added); *see also* Tr. 1, 137:13–138:16. 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.[88] Tr. 1, 138:17–21.

These methodological flaws and lack of peer review render Dr. Mannen's testimony totally unreliable. Indeed, whether an expert's work has been "accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, *i.e.*, that it meets at least the minimal criteria of good science." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (*Daubert II*); *see also Williams v. Invenergy, LLC*, No. 2:13-CV-01391-AC, 2016 WL 1725990, at *11 (D. Or. Apr. 28, 2016) (distinguishing between (1) "editorial" peer review, in which as "the average [peer-reviewing] referee spends less than two hours assessing an article submitted" and (2) "true peer review," which is "is the process by which an author's peers review the author's methods and attempt to replicate the results through retesting") (citations omitted); *Valentine v. Pioneer Chlor Alkali Co.*, 921 F.Supp. 666, 674–76 (D. Nev. 1996) (same). None of Dr. Mannen's methods and results here have met this "minimal criteria of good science."

Dr. Mannen's unproven tools and speculative conclusions provide no basis to support Complaint Counsel's allegations.[89]

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[88] At least three courts have rejected Leshner's technique as lacking a reliable methodology and validation. *See Rovid v. Graco Children's Prod. Inc.*, No. 17-CV-01506-PJH, 2018 WL 5906075, at *7 (N.D. Cal. Nov. 9, 2018); *McKerrow v. Buyers Prods. Co.*, No. CCB-14-2865, 2016 WL 1110303, at *3 (D. Md. Mar. 22, 2016) (excluding Leshner's opinions); *Brodsky v. KaVo Dental Techs., LLC*, No. PX 15-3587, 2018 WL 620453, at *3 (D. Md. Jan. 30, 2018) (excluding Leshner's opinion because it "lacks any reliable methodology ... [and is] inadmissible without underlying validation").

[89] As explained in Leachco's Cross-Appeal Brief, Dr. Mannen's testimony should have been excluded in its entirety. Regardless, the Presiding Officer properly gave it little weight due to the crucial failure to follow scientifically validated testing methods.

d. Complaint Counsel omits material context.

In its brief, Complaint Counsel claims that, according to Dr. Mannen, "by virtue of their design, Podsters 'exhibited *over 10 times less airflow* ... compared to the recommended threshold.'" CPSC Br. 36 (quoting CCX-1, p. 48). What Complaint Counsel omits is the rest of that sentence from Dr. Mannen's report. The full sentence states: "Airflow Testing revealed that the Leachco Podster pillows exhibited *over 10 times less airflow* (shown here as an increase in pressure) compared to the recommended threshold of 0.31 in H_2O **established as part of our previous research** on crib bumper and mesh liner products (Figure 15)." CCX-1, p. 48 (bold emphasis added). Thus, again, Dr. Mannen has not identified a scientifically validated threshold; she merely points to a CPSC-sponsored study that she led (Mannen 2023)—another study whose methods, thresholds, and results have not been peer-reviewed or validated. Complaint Counsel's omission here is damning; it falsely suggests that Dr. Mannen used an objective, validated threshold for airflow, when in fact she again relies on her own non-peer-reviewed and non-validated research. Her testimony is, therefore, unreliable. *See Zenith Electronics Corp. v. WH-TV Broadcasting Corp.*, 395 F.3d 416, 419 (7th Cir. 2005) ("A witness who invokes 'my expertise' rather than analytic strategies widely used by specialists is not an expert as Rule 702 defines that term.").

Another example: Complaint Counsel misleads when it claims, the "main conclusion is that the design of the Podster causes an increase of nearly 2.5 times the amount of CO_2 rebreathing as compared to *a control group*." CPSC Br. 36 (emphasis added). But Dr. Mannen didn't use a control group. Instead, employing non-peer-reviewed and non-validated measurement techniques, she

compared results from the Podster and from a mattress. CCX-1, pp. 27–28, 49; Tr. 1, 131:14–16; 135:4–7.

4. Complaint Counsel's comparison of products distinct from the Podster fails to establish that the Podster is defective.

As the Presiding Officer concluded, Complaint Counsel failed to show that the Podster's "non-conformance to an idealized sleep surface [that the Commission] has approved is a 'defect.'" Initial Decision 57. Instead, Complaint Counsel argued that the product has a "fault, flaw, or irregularity" which allegedly "impairs [its] quality, function, or utility" because it is not designed as a CPSC-approved sleep product. *Id.* 40. But Complaint Counsel introduced no evidence of a comparable and safer *infant lounger*—a class of products that has not been banned by the Commission—that would prove a "reasonable alternative design."[90] *Id.* Indeed, at the hearing, Complaint Counsel did not "discuss[] or suggest[]" an alternative design that would "remediate" the alleged "imperfection" that "could have reduced or avoided a foreseeable risk of harm" to anyone. *Id.* 40–41.[91]

Further, Complaint Counsel introduced no evidence that the Podster is substantially dangerous for its intended use. Instead, Complaint Counsel's expert witness, Dr. Mannen, compared the Podster with infant sleep products—an entirely different class of products. Accordingly, Dr. Mannen's conclusion,

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[90] As Complaint Counsel's expert admitted, the Commission's own rulemaking explicitly refused to ban infant loungers while banning certain infant sleep products. Tr. 2, 36:1–9 (Kish).

[91] *See also* Initial Decision 46 (Complaint Counsel's "failure to consider the Podster's form and function in service of its utility resulted in a product safety case where no Commission witness suggested an alternative, safer design, except to state that the products should effectively conform to the form and material used in flat crib mattresses.") (citations omitted); *see also id.* ("Similarly, the Complaint faults the [Podster's] lack of a rigid frame structure in the abstract, but Complaint Counsel did not present any evidence showing that an alternative design featuring such framework would have been safer.").

that the Podsters are defective, is "unpersuasive because it entirely fail[ed] to account for an important distinction between the Podsters and the inclined sleep products she tested and relied on" since those products were designed and intended "for sleep." Initial Decision 41. And the "Commission has acknowledged from the beginning—in [its] Complaint—that the Podster is not marketed for use as and has never been advertised as a sleep product." *Id.* (citing Compl., ¶¶13–14).

As the Initial Decision suggests, Complaint Counsel has erroneously portrayed the Podster as a *de facto* sleep product. It has done so by citing potential "foreseeable misuse" (for sleep).[92] But that says nothing about the Podster's being dangerous for its intended use. Indeed, the "factual differences" between the products are stark. Sleep products are intended to be primarily used at night when supervision is less likely, while the Podster and infant loungers generally are designed for supervised awake time. *See* Initial Decision 41–42. At bottom under the CPSA, correctly applied,

> [t]he absence of evidence of a safer alternative design or a safer product within the class of infant loungers, alone, may therefore be sufficient to refute the existence of a design defect in the Podsters, based on the common understanding of the terms "defect" and "design defect." *See* Restatement (Third) of Torts: Product Liability, §2(b) (Am. Law Inst. 1998) (design defect exists where foreseeable risks of harm could have been avoided or diminished by adoption of reasonable alternative design, the omission of which renders the product not reasonably safe). Complaint Counsel's own witnesses believe that there is no way to improve the product, and no way to effectively warn against its supposed dangers, which are hardly manifest or obvious, and which required three experts

[92] As Leachco has explained throughout this proceeding, and more fully explained below, long-standing legal principles foreclose Complaint Counsel's attempt to radically reformulate what constitutes a "product defect."

> together to gather a theory of prospective harm threatened by the misuse of the product.

Id. 43.

5. The Podster is not defectively designed under the CPSC's non-binding regulation.

The Podster is not defective under the ordinary and common-law meaning of the CPSA. Nor is it defectively designed under the CPSC's own (non-binding) regulations. Initial Decision 43–56.

a. As the Initial Decision noted, 16 C.F.R. § 1115.4 has been found to guide the Commission's "defect" determination. *See* Initial Decision 43 (citing cases). Under § 1115.4, the Commission will consider, as it deems appropriate, 11 factors to determine whether a productive is defective:

> (1) [t]he utility of the product involved;
> (2) the nature of the risk of injury which the product presents;
> (3) the necessity for the product;
> (4) the population exposed to the product and its risk of injury;
> (5) the obviousness of such risk;
> (6) the adequacy of warnings and instructions to mitigate such risk;
> (7) the role of consumer misuse of the product and the foreseeability of such misuse;
> (8) the Commission's own experience and expertise;
> (9) the case law interpreting Federal and State public health and safety statutes;
> (10) the case law in the area of products liability; and
> (11) other factors relevant to the determination.

16 C.F.R. § 1115.4.

The Presiding Officer considered these factors and concluded that Complaint Counsel failed to prove the Podster is defectively designed. That holding should be affirmed.

i. The Commission failed to show the Podster provides no utility.

Complaint Counsel asserts that the Podster provides "no utility." But as the Presiding Officer observed, this is "disproved by economic data" and by "common sense." Initial Decision 44. "[T]housands of consumers" have purchased the Podster since it came to market in 2009; it both identified and fulfilled a "consumer need." *Id.* Moreover, the Podster's utility was shown not only by economic data and common sense, but also by Complaint Counsel's own expert: "Somewhat ironically, Kish's recitation from *New York Magazine's* product review blog may provide the best illustrative support for the Podster's form serving its function[.]" *Id.* As that article explained:

> Holding and feeding your baby all the time is exhausting. The little nugget spits up post-feeding and you don't want to lay them flat all the time because "flat head syndrome" is a real thing. Hence this pod. The sides are contoured so the baby is snug, secure, and also slightly elevated. ... No other seat out there "snuggles" the baby like this one.

Id.

The "Podster is a niche product, designed to fill a limited supportive role for caregivers who need a place to rest an infant for short intervals during the day." Initial Decision 46. Yet the "Commission utterly fails to address this utility of the product for its intended use, except to disparage it in comparison with approved sleep mattresses or by association with sleep products—a category with a different intended use—which it has characterized as dangerous, and which have now been banned." *Id.* Complaint Counsel needed to confront the "balance of" the Podster's "utility" with any "associated potential risk" but it failed to do so. *See id.*

ii. The Commission fails to show infants are vulnerable through isolated and unproven incidents of misuse of the product.

The Presiding Officer noted that, although infants are a vulnerable population, Complaint Counsel failed to show they are vulnerable because of any design defect with the Podster. Indeed, Complaint Counsel failed to address the "role of caregivers, their responsibility, and whether they generally safeguard infants against the risks of injury from misuse of the product." Initial Decision 47. And Complaint Counsel's experts cannot "quantify" or attest to how or when caregivers might misuse the Podster or when using the Podster is safe. *Id*. Further, what "can be—and has been—quantified is the number of injuries resulting from misuse of the product." *Id*. And "that number is, at most, three in more than 12 years." *Id*. Yet "even that number is questionable." *Id*. Indeed, Complaint Counsel can prove neither that the Podster caused incidents it relies on in its self-developed IDIs, nor that a design defect in the Podster created any risk of injury, much less a substantial one.

As the Presiding Officer observed, the IDIs reflect "incidents where a Podster had been present when an infant died." Initial Decision 10.[93] The IDIs do not establish, however, that the Podster caused any of the three deaths. Likely for this reason, Complaint Counsel barely mentions them—instead citing the entire IDIs, *see* CPSC Br. 19 n.17, or flying through the facts, *see id*. 60–61—and hoping others infer causation. But, as the Presiding Officer observed, the most that can be inferred here tragically is that three infants, all experiencing

[93] The Presiding Officer excluded hearsay documents contained within the IDIs, namely documents reflecting comments, or summaries thereof, from third parties. *See* Order Deferring Decision on Complaint Counsel's Mot. in Limine & Memo. in Support to Admit IDIs, Dkt. 129, p. 2. As explained below, these documents were properly excluded from evidence. Further, as set forth in Leachco's Cross-Appeal Brief, additional hearsay documents in the IDIs should have been excluded.

some kind of breathing or congestion problems, died when caregivers engaged in unsafe-sleep practices unrelated to the Podster. Put differently, Complaint Counsel showed that caregivers in three instances engaged in unsafe-sleep practices that had nothing to do with the design of the Podster. *See* Initial Decision 23, 32–33, 47–48, 50–51, 54, 56–57, 59–64.

1. In the **Alabama Incident**, the evidence showed that daycare personnel placed an infant weighing over 16 pounds (too big for the Podster), with a bottle in his mouth, in a Podster in a crib along with blankets and a soft object, for an unsupervised nap. Initial Decision 32; JX-07, pp. 2, 49–51, 56, 58. The Commission's IDI says it "is unclear what position the boy was placed"—his back, front, or side—on the lounger. JX-07, pp. 2. 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. *Id*. at 24. After an unknown amount of time, a daycare employee noticed the infant making gurgling sounds. *Id*. at 2. It is not clear in what position the baby was found; he may have been face-down or on his back. *Id*.

According to the Commission's IDI, "the [state's] daycare licensing agency suspended the daycare's license because of the imminent danger to the health, safety, and welfare of the children who attend the daycare. The suspension letter sent to the daycare [] cites the incident described above as well as numerous 'deficiencies' observed during visits made after the incident." *Id*. Among other things, the required ratio of staff to infants was regularly ignored, an infant was found in a crib with a plastic potato chip bag, and blankets and other soft materials were placed in cribs with infants. JX-07, p. 11. As a result, the

daycare's license for that location was revoked, and that location was closed. *Id.* at 12. 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." *Id.* at 18.

2. Similar unsafe-sleep practices were present in the **Texas Incident**. Initial Decision 23, 32, 51. There, according to hearsay documents, the mother of a 17-day-old girl, 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" between the mother and father, and the mother fell asleep. JX-09, p. 33. A police report 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. *Id.* The mother saw the father raise the bed sheet and observed the victim lying on her back, cold to the touch and unresponsive. *Id.* According to a follow-up interview by the police, both parents said that the baby slept with them on her "pink pillow" between them. *Id.* at 34.

Other hearsay statements in the Texas IDI, however, show inconsistencies. Most notably, the mother also said she "fed the victim at 2 am and went back to sleep." *Id.* But here, the mother did *not* say that she placed the victim *back in the* "*pillow*." *See* JX-09, p. 34. And Complaint Counsel's experts—Dr. Katwa and Ms. Kish—acknowledged the possibility that the mother fed the baby and fell asleep without placing the baby in the Podster. Tr. 3, 23:7–13 (Katwa); Tr. 2, 71:1–6 (Kish). They both further acknowledged the close connection between breastfeeding and mothers' co-sleeping with their babies. Tr. 3, 23:14–17 (Katwa); Tr. 2, 65:18–66:3 (Kish). Indeed, Ms. Kish's report

relies on a study that confirms this connection.[94] CCX-2 (Kish Report), p. 60 n.114 (citing Drago study). 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. Tr. 2, 64:18–66:3.

The mother also said that she "got up at 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." JX-09, p. 34. The baby's lower body was apparently covered by a blanket. JX-09, p. 19. Pictures purportedly from the scene show several infant products, including a baby bouncer and three different infant loungers. Initial Decision 51; JX-09, pp. 45, 48. There also appears to be an empty bottle of beer in the trash can. JX-09, pp. 48. Apparently, the infant had been making gasping sounds and was scheduled for a doctor's appointment two days after she passed away. JX-09, pp. 4, 22.

Ultimately, the manner of death was certified by the Medical Examiner as "undetermined." JX-09, p. 13. But positional asphyxia due to "co-sleeping in an unsafe sleep environment" could not be excluded "as contributory." *Id.*

3. Finally, the **Virginia Incident,** too, involved unsafe sleep practices, here by an in-home daycare. Initial Decision 14–15, 23, 31, 33. After a three-month-old infant was dropped off at the daycare, she was placed in a Podster—in a play yard or play pen, with a nursing blanket—for an unsupervised nap. JX-11, pp. 6, 11. She was propped up in the Podster because she had "so much congestion." *Id.* at 11. Approximately 45 minutes later, the husband, who ran the daycare with his wife, noticed the infant had turned over slightly, but still

[94] Drago, et al., "Infant fatality patterns in shared sleep: keys to intervention strategies?" Proceedings of the 2021 HFES 65th International Annual Meeting, 1322–1326 (2021).

primarily lying on her back. *Id.* at 51. 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. *Id.*[95] When he approached to move her, he noticed that her body was limp. *Id.* He screamed, took her to a couch, and performed CPR. *Id.* at 11. 911 was called, and the infant was taken to a hospital, where tragically she was pronounced dead. *Id.*

The Virginia IDI shows that the infant had been sick. According to the autopsy report, the Virginia infant had chronic bronchitis. JX-12(A), p. 5. A week before she passed away, she was taken to a doctor for congestion. *Id.* at 9. The infant also had a possible ear infection. *Id.* at 8. The infant was taking Albuterol. *Id.* And she had been sick for several days. JX-11, p. 11. A week before the incident, she had been taken to a pediatrician because she was "very congested;" and she was prescribed respiratory treatments for breathing/wheezing. *Id.* Two days before the incident, the infant's mother called 911 because the infant was having trouble breathing. *Id.* She was "very congested," had vomited mucus, and had a "difficult time" breathing. *Id.* According to the autopsy report, the cause of death was "[s]udden unexpected infant death with unsafe bedding and positioning," and the manner of death was "[u]ndetermined." JX-12A(1), pp. 3, 5.

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Unfortunately, "between 1,000 and 3,500 infants die unexpectedly in their sleep each year." Initial Decision 47. And Complaint Counsel's own expert Dr.

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[95] According to the IDI, a "reenactment" with a doll purports to show the face of the doll against the side of the Podster, JX-11, p. 35, but as the CPSC's Ms. Kish testified, "it is not known whether the victim's face was actually in this position," CCX-2 (Kish Report), pp. 72–73; *see also* Tr. 2, 71:7–18 (Kish). And Ms. Kish admitted that no evidence shows whether the infant's face was in the position that the doll reenactment purported to show. Tr. 2, 71:19–22 (Kish).

Mannen's studies show that it is in fact several unsafe sleep factors that are the primary reason that infants tragically die each year. *See id*. 48. Moreover, while there is no evidence to directly link the Podster's design to a substantial risk of injury, there is strong evidence that infant deaths are attributable to caregiver misuse and "unsafe sleep environments" like co-sleeping. *Id.*

At bottom, the "data" does not show that the Podster's design is inherently dangerous, Initial Decision 48, and infants are only "at risk if safe sleep procedures are disregarded," *id.*, which is the "more substantial threat to public safety," *id*. 49. The "evidence of record" thus does not show a "pattern of defect" with the Podster that "creates a danger" to vulnerable infants.[96]

C. Complaint Counsel failed to prove—even if it had established a defect—that any such defect created a substantial risk of injury to the public.

Because Complaint Counsel failed to prove that the Podster has a design defect, Initial Decision 43–56, the Commission need not go further to affirm the Presiding Officer's Initial Decision. But even if Complaint Counsel had proved the Podster is defective—it has not—Complaint Counsel still failed to show that its supposed defect "creates"—*i.e.*, causes—a "substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2). *See* Initial Decision 56–64. Its complaint may be independently dismissed on these grounds.

Complaint Counsel had the burden to prove that "because of" the "pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise," the Podster "creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2). *See* July 6, 2023 Order, Dkt. No. 99, p. 3

[96] Because Complaint Counsel failed to prove that the Podster is a substantial product hazard, its argument for an order requiring Leachco to recall the product (CPSC Br. 62) should be rejected.

("Complaint Counsel is still required to demonstrate the alleged defect's creation of that risk."); *id*. at 8 (Complaint Counsel "must ... demonstrate that that injury is the result of the alleged defect."). Here, "the ordinary meaning of 'because of'" incorporates the standard of but-for causation, *Bostock*, 140 S.Ct. at 1739, 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).

Again, the common law supports these ordinary understandings. *See, e.g.*, *Zepik,* 856 F.2d at 942 ('[G]iven the CPSA's structure and legislative history no plausible federal standard could deviate so radically from established concepts of causation in tort."). This long-standing tradition includes not only but-for causation, but also proximate cause. *See, e.g.*, *Kirkbride v. Terex USA, LLC*, 798 F.3d 1343, 1349 (10th Cir. 2015) ("[I]f the event which produced the injury would have occurred regardless of the defendant's conduct, then the failure to provide a warning is not the proximate cause of the harm and the plaintiff's claim must fail.") (quoting *House v. Armour of Am., Inc.*, 929 P.2d 340, 346 (Utah 1996) (internal quotation marks omitted)); Dan B. Dobbs, *Law of Torts* § 451 (West Group, 2000) (identifying requirements to establish a defect: both cause-in-fact and proximate or legal cause); *see also Zepik,* 856 F.2d at 942 ("The CPSA does not elaborate on the meaning of 'by reason of,' but in the absence of any indication that Congress intended to depart from conventional notions of causation we think the causal connection required here should be roughly equivalent to the causal connection *required to establish common law tort liability*.") (emphasis added).

Complaint Counsel has failed to prove that the Podster was the but-for or proximate cause of any harm to anyone.[97] Nor, even under the standard applied by the Presiding Officer, did Complaint Counsel prove that the Podster (if defective) creates a "substantial risk to the public":

> To "create" is to "bring into existence;" to "produce or bring about by a course of action or behavior;" or "to cause or occasion." Create, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/create (last updated June 21, 2024). Thus, the substantial risk of injury must actually exist, and it must have been "brought into existence," "produced or brought about by" or "caused" by a defect in the design of the Podster.

Initial Decision 56–57.

The Podster was put on the market in 2009 and since then at least 180,000 have been sold. In that time, those Podsters have likely been used "millions" if not "tens of millions" of times. Initial Decision 59. Yet contra Complaint Counsel's experts' assertions that a substantial risk of injury exists because, say, it is "easy" for infants to move into dangerous positions on the Podster, Complaint Counsel offered no evidence that this risk has ever materialized. *Id*. The evidence suggests only that the three incidents involved people who had a Podster. *Id*. But what the evidence unmistakably *proves* is that the three incidents involved "unsafe sleep environment[s]" with "compound hazards." *Id.* And Complaint Counsel presented *zero* evidence that *the Podster's design*—or any product—created a "risk of injury" much less a "substantial" risk. *See id.* 60 ("Nowhere in Complaint Counsel's case is there a basis for concluding that a substantial risk of injury has been created by the Podster's design.").

[97] *See* Leachco's Post-Hearing Brief, Dkt. No. 144, 86–95.

Second, the CPSC's "own data" refutes that the Podster "created" or caused substantial risk of injury to the public. Initial Decision 60. Instead, Commission reports 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 reveal that most of these deaths occur—even in CPSC-approved cribs and bassinets—*because of unsafe-sleep environments*. *See id*. at pp. 152–53. The Commission's expert witnesses, Ms. Kish and Dr. Umakanth Katwa, acknowledged these facts. *See* Tr. 2, 91:21 (Kish); Tr. 3, 14:6−15, 47:6–8 (Katwa).

Third, Complaint Counsel's proffered evidence about the three incidents showed not that the Podster created any risk of injury, but rather "unsafe sleep environments." Initial Decision 60.

* * *

The evidence establishes overwhelmingly that unsafe-sleep practices—and not any product—caused the heartbreaking deaths here. Complaint Counsel offered no reliable evidence to demonstrate that the Podster has (1) a product defect (2) that creates (3) a substantial risk of injury to the public. Likely for that reason, Complaint Counsel attempts to undermine the Initial Decision's legal analysis. As explained next, Complaint Counsel's arguments fail.

II. COMPLAINT COUNSEL'S ARGUMENT OVER WHAT CONSTITUTES A DESIGN DEFECT IS WRONG.

Complaint Counsel makes several wrong assertions over the Presiding Officer's interpretation of the CPSA, and the regulations implemented under it, concerning how to determine if a product is defective.

First, the Presiding Officer did not "apply" an "unreasonable risk" analysis in his Initial Decision. CPSC Br. 7; *see generally id*. 6–9. Indeed, in instances where the Presiding Officer discussed "unreasonable risk," he either (1) provided background information about the Commission's powers and mission or (2) explained that he was *not* applying that standard to the facts here. For example, in the section titled, "The CPSC's Authority," the Presiding Officer merely gave a background of the statute. Initial Decision 37–38 (describing the CPSA's "purpose" and discussing how the CPSC may ban a product through rulemaking); *see also id.* 37 n.24 (describing CPSA's "legislative history"). Immediately after, the Presiding Officer discusses the standard to determine whether a "substantial product hazard" exists—based on a "substantial risk of injury to the public." *Id*. 38. The Presiding Officer then (*id*. 38–39) cites 16 C.F.R. § 1115.4, which Complaint Counsel itself argues is relevant to the "substantial product hazard" analysis. *See, e.g.*, CPSC Br. 32. Similarly, the Initial Decision's references to rulemaking cases did not, contrary to Complaint Counsel's assertion (CPSC Br. 6–9), impose on Complaint Counsel an "unreasonable risk of injury" burden. Again, the Presiding Officer explained that "while both legal actions [common law and the CPSA] include consideration of "unreasonable risk of injury, the Commission is not bound by the requirement to establish the same elements as a plaintiff in a private cause of action." Initial Decision 52–53. And the Presiding Officer referenced the "foreseeable" and "substantial" risk of harm throughout the Initial Decision. *See, e.g.*, *id*. 3, 5–6, 38, 40–41, 43, 50, 56–57, 60, 62–64.

At worst, the Presiding Officer applied both a "substantial risk" and an "unreasonable risk" analysis. *See* Initial Decision 50 ("Complaint Counsel must

at least prove that the design of the product contributes to misuse, so that there is a demonstrated link between misuse and design sufficient to establish a 'substantial risk of injury to the public,' *or* an unreasonable risk of injury, created by the design.") (emphasis added). But if that was error, it was harmless error—because the Presiding Officer concluded that Complaint Counsel failed to establish a defect (under either standard). *See, e.g.*, *id*. 60 ("Nowhere in Complaint Counsel's case is there a basis for concluding that a *substantial risk* of injury has been created by the Podster's design.") (emphasis added); *id*. ("The data do not support a *substantial risk* of injury to the public *created* by a defect in the Podster, *as the standard requires* ….") (some emphasis added).

> Indeed, in the Presiding Officer's Conclusion, he states expressly:
>
> As set forth in this decision, the Commission has not demonstrated by a preponderance of the evidence that the Podsters have a substantial design or other defect and, even if a defect might be found to exist in some technical sense, the Commission has also failed to demonstrate that such defect creates or has created a *substantial risk* of injury to the public.

Initial Decision 65 (emphasis added). Complaint Counsel's arguments here are an attempted distraction from its failure to prove its case.

Second, Complaint Counsel argues that the Presiding Officer erred by improperly looking to "state product liability law" and general product liability law. CPSC Br. 11–15. This argument is wholly without merit. As explained above, long-standing canons of statutory interpretation require looking at the commonly understood meaning of undefined terms. *See supra* pp. 18–19. Further, the Commission's own regulations say expressly that a defect analysis considers "the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and other factors relevant to the determination." 16 C.F.R. § 1115.4. The Presiding Officer's consideration

of product-liability law was proper. Complaint Counsel concedes as much—in a footnote—but claims such consideration is limited suits in which design "aspects have been found to constitute product defects in product liability suits." CPSC Br. 12 n.18 (quoting 43 Fed. Reg. 34,988, 34,991 (Aug. 7, 1978)). This quotation is taken out of context. It was responding to a commentator's objection "to the kinds of 'aspects' of consumer products which the Commission felt could be defective." 43 Fed. Reg. at 34,991. In response, the Commission noted that various "aspects have been found to constitute product defects in product liability suits." *Id*. Therefore, "those aspects of products which are accepted by the courts as presenting unreasonable risks, *as well as* those discussed specifically in § 1115.4, would be defective within the meaning of section 15 of the CPSA." *Id*. (emphasis added). Finally, the Commission explained, "[o]f course, neither the regulation nor judicial determinations constitute the definitive statement as to which aspects of consumer products may be found to be defective. Such a determination is made on a case-by-case basis." *Id*. In short, the Commission did not limit the use of product-liability cases as Complaint Counsel suggests. Indeed, as the Commission's response points out, such a limitation would prevent Complaint Counsel from establishing defects on a case-by-case basis.

Third, Complaint Counsel asserts (CPSC Br. 18–23) that the Presiding Officer "mischaracterizes Section 15's substantial product hazard standard" by comparing the Podster to other products. This is a red herring. Complaint Counsel's entire case is based on comparisons of (1) the Podster and, among other things, (2) inclined sleepers and mattresses. The Presiding Officer correctly pointed this out:

> Mannen's conclusion about the Podsters is unpersuasive because it entirely fails to account for an important distinction between the Podsters and the inclined *sleep products* she tested and relied on in reaching her conclusion: the inclined *sleep products* were intended for sleep. See CCX-1, at 33 ("One can conclude that the Leachco Podster is dangerous in manners similar to how those inclined sleep products were found to be dangerous.") But the Commission has acknowledged from the beginning—in the Complaint—that the Podster is not marketed for use as and has never been advertised as a sleep product. Compl., ¶¶13–14.

Initial Decision 41 (emphasis added). His comparison of products was thus prompted by Complaint Counsel's case.

Finally, contrary to Complaint Counsel's argument (CPSC Br. 15–16 (citing Initial Decision 47)), the Presiding Officer did not require a "threshold of actual deaths" to determine that the Podster had a defect. Indeed, on the very page cited by Complaint Counsel, the Presiding Officer states, the "Commission does not need to prove that the Podster actually caused any of the three deaths to which Complaint Counsel has related its use." Initial Decision 47. He went to consider the deaths and other evidence while discussing the potential risk. Ultimately, the Presiding Officer concluded—based on the evidence produced by Complaint Counsel—that, even if a defect exists in some technical sense, such a defect does not create a substantial risk of injury to the public. *Id*. 65.

III. THE COMMISSION'S READING OF THE CPSA VIOLATES THE MAJOR QUESTIONS DOCTRINE, THE NONDELEGATION DOCTRINE, AND IS VOID FOR VAGUENESS.

A. Congress did not give the Commission a roving license to ban lawful consumer products.

Complaint Counsel's asserted theory (CPSC Br. 16–17)—that customers' misuse "solely" can create a "defect" in a product and that there need be no determination of whether a product actually creates a "substantial risk of injury"—invites the Commission to adopt a novel and radical view of the

Commission's powers under the CPSA. But these views are found neither in the statute nor within traditional legal regimes. The Commission should reject Complaint Counsel's invitation.

Complaint Counsel's assertion of power fits within an all-too-common pattern that has developed in the modern administrative state. By seeking to redefine "product defect" and expansively and unreasonably construe "substantial risk of injury," Complaint Counsel is trying to "discover in a long-extant statute an unheralded power representing a transformative expansion in its regulatory authority." *West Virginia v. EPA*, 597 U.S. 697, 724 (2022) (cleaned up). But the Supreme Court has repeatedly held that under the Major Questions Doctrine, "Congress [must] speak clearly when authorizing an agency to exercise powers of vast economic and political significance." *Nat'l Fed'n of Indep. Bus. v. OSHA*, 595 U.S. 109, 117 (2022). Complaint Counsel's view would, if adopted, allow the Commission to ban virtually every product on the market.

Indeed, the implications of the Commission's view of its authority under the CPSA here cannot be overstated. If a "product defect" can be found in a consumer product that (1) is safe as designed for its intended use and (2) contains express warnings against foreseeable misuse, then the Commission's already extensive recall authority will be subject to no limiting principle. But there is nothing in the CPSA that gives the CPSC this kind of "roving commission," *Michigan v. EPA*, 268 F.3d 1075, 1084 (D.C. Cir. 2001), to eliminate insignificant risks at enormous costs. And Congress no doubt would have used much clearer language had it wanted to stretch CPSC's product hazard authority to every consumer good. *See Sackett v. Env't Prot. Agency*, 598 U.S. 651, 677 (2023) (Congress does not "tuck[] an important expansion to the

reach of" a federal agency's power "into convoluted language"—or "hide elephants in mouseholes.").

Importantly, products subject to actions under § 2064(a)(2) that do not violate any regulatory ban—like the Podster here[98]—are *legal*. As a former Commissioner has explained, under § 2064(a)(2), "the Commission seeks to remove an *otherwise legal* product from the marketplace." Robert Adler & Andrew F. Popper, *The Misuse of Product Misuse: Victim Blaming at its Worst*, 10 Wm. & Mary Bus. L. Rev. 337, 355 n.94 (2019) (emphasis added). Therefore, if Congress intended to give the CPSC power to force a manufacturer to recall a product that has (1) no manufacturing defect, (2) no warning defect, (3) no design defect that renders the product unsafe for its intended use, and (4) an infinitesimally small likelihood of injury—if Congress truly wanted to give the CPSC such vast power, it would have "enact[ed] exceedingly clear language … to significantly alter the … power of the Government over private property." *United States Forest Service v. Cowpasture River Pres. Ass'n*, 590 U.S. 604, 621–22 (2020). The Commission's claim of such authority—to take any consumer product off the market regardless of whether the product ever caused an injury, or without having to prove any likelihood of injury, would constitute authority of "economic and political significance," which "provide[s] a reason to hesitate before concluding that Congress meant to confer such authority." *West Virginia*, 597 U.S. at 721 (cleaned up). Even if the Commission could argue that the CPSA provided "a vague statutory grant" of power, such a grant "is not close to the sort of clear authorization required by [Supreme Court] precedents." *Id.* at 732.

[98] *See* Initial Decision 24.

Accordingly, Complaint Counsel's plea for the Commission to rewrite the CPSA and increase its authority must be rejected.

B. If Congress did give the Commission a roving license to ban consumer products, then the CPSA violates the Nondelegation Doctrine.

The Constitution prohibits Congress from giving away its lawmaking powers. *Jarkesy v. SEC*, 34 F.4th 446, 460 (5th Cir. 2022), *aff'd*, 144 S.Ct. 2117 (2024). As Chief Justice Marshall put it, Congress must decide the "important subjects." *Wayman v. Southard*, 23 U.S. (10 Wheat) 1, 43 (1825). Thus, Congress must make "fundamental policy decisions" itself—"the hard choices." *Indus. Union Dep't v. Am. Petroleum Inst.*, 448 U.S. 607, 687 (1980) (Rehnquist, J., concurring in the judgment). And cabining congressional delegations within proper bounds remains "vital to the integrity and maintenance" of the Constitution's structure. *Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1982); *see also Gundy v. United States*, 588 U.S. 128, 152–54 (2019) (Gorsuch, J., dissenting).

Here, Complaint Counsel claims the authority to create new definitions of "product defect" and thereby ban any product that presents any "risk of injury." *See* CPSC Br. 32–41. As explained above, Leachco submits that under traditional canons of statutory interpretation, the CPSA does not grant the Commission the sweeping authority its interpretation would require. Courts should not invalidate statutes on constitutional grounds if a limiting construction is "fairly possible"—courts should construe statutes "to avoid not only the conclusion that it is unconstitutional but also grave doubts upon that score." *Almendarez-Torres v. United States*, 523 U.S. 224, 237–38 (1998) (citation omitted). In this way, unless "plainly contrary to the intent of

Congress," courts should reject constructions that "would raise serious constitutional problems" even if they are "otherwise acceptable." *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 173 (2001). But if the Commission agrees with Complaint Counsel's interpretation, then the CPSA violates the nondelegation doctrine.

Under that doctrine, the statutory text must provide an "intelligible principle" to properly direct executive agencies. *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 472–73 (2001). In *Panama Refining Co. v. Ryan*, the Supreme Court found a provision of the National Recovery Act unconstitutional because it gave unfettered discretion to the President to decide whether and under what conditions to prohibit the transport of hot oil. 293 U.S. 388, 430 (1935). Notwithstanding the law's general goal of improving American economic conditions, it was ruled unconstitutional because Congress made no policy decision. *Id.* at 416–18. Instead, Congress allowed the President to weigh competing policy considerations as he declared "fit." *Id.* at 415.

Here, the Commission should reject Complaint Counsel's interpretation that the CPSA grants it unfettered discretion to (re-)define "product defect" and "substantial risk of injury" as it deems fit. Agencies may fill in details with "judgments of degree," *Whitman*, 531 U.S. at 475, but Congress cannot allow agencies to set "the criteria against which to measure" their own decisions, *Gundy*, 588 U.S. at 166 (Gorsuch, J., dissenting). Instead, Congress must be "sufficiently definite and precise" so courts can easily determine when an agency exceeds its authorized power. *Yakus v. United States*, 321 U.S. 414, 426 (1944).

The Constitution therefore demands "substantial" guidance for standards that would—under the Commission's interpretation—have the potential to

"affect the entire national economy." *Whitman*, 531 U.S. at 475; *see also Michigan v. EPA*, 576 U.S. 743, 762–63 (2015) (Thomas, J., concurring) (noting "potentially unconstitutional delegation[]" if EPA had unfettered discretion over "which policy goals" it pursued).

Properly interpreted and applied, § 2064(a)(2) likely does not unlawfully delegate legislative power to the Commission. Reading the statute's plain terms according to their ordinary and common-law meanings—(1) a "product defect" is a manufacturing, design, or warning defect, and (2) such a defect must *cause* (3) a "substantial" (*i.e.*, highly likely) *risk* of death, injury, or serious or recurring illness—properly limits the Commission's authority to execute rather than make the law. Those standards provide the Commission with an "intelligible" standard to apply and which the Presiding Officer largely observed in his Initial Decision.

But without these guardrails, the CPSA is, at bottom, a "delegation running riot." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 553 (1935) (Cardozo, J., concurring). Therefore, if Complaint Counsel's reading of § 2064(a)(2) is correct, the statute constitutes an unlawful delegation of legislative power.

C. Defining "product defect" to allow the Commission to ban products based on "foreseeable misuse," despite warnings and instructions, makes the CPSA unconstitutionally vague.

According to the Supreme Court, the law "assume[s] that man is free to steer between lawful and unlawful conduct," and thus the Court has "insist[ed] that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). Therefore, a regulatory regime that purports

to impose liability based on either a radical rewriting of statutory text or after-the-fact discretionary fiat runs afoul of the Due Process Clause. *Id.*

As explained above, Complaint Counsel's proposed revisions to the CPSA would not only represent an unwarranted power-grab by the agency, but it would also effect a dramatic change in the CPSA itself and the common law on which it was based. *Cf. Zepik*, 856 F.2d at 942. That alone would violate Leachco's due process rights.

But worse, Complaint Counsel erroneously relies on 16 C.F.R. § 1115.4.[99] Section 1115.4 is—as the Commission admits[100]—merely an interpretive rule. And "interpretive rules, even when given *Auer* deference, do *not* have the force of law." *Kisor v. Wilke*, 588 U.S. 558, 583–84 (2019) (plurality op.) (citing *Perez v. Mortgage Bankers Ass'n*, 572 U.S. 92, 97 (2015) ("Interpretive rules do not have the force and effect of law and are not accorded that weight in the adjudicatory process.") (cleaned up)). Therefore, an "interpretive rule itself never forms the basis for an enforcement action—because such a rule does not impose any legally binding requirements on private parties." *Id.* (cleaned up).

But, even if § 1115.4 did apply to § 2064(a)(2) and assuming it is not merely interpretive guidance, § 1115.4 would unlawfully allow the Commission to determine—after the fact—that a product is defective based on a non-exhaustive list of factors that the Commission and its staff, at their discretion, might apply. Thus, according to § 1115.4, "the Commission and staff will consider *as appropriate*:"

> The utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the

[99] *See, e.g.*, Compl., ¶¶45, 47 (citing 16 C.F.R. § 1115.4).
[100] *See* CPSC Supp. Resp. to Leachco RFA, No. 275.

> obviousness of such risk; the adequacy of warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and *other factors relevant to the determination*.

16 C.F.R. § 1115.4(e) (emphasis added).

Thus, the Commission allows itself to consider various factors *as it deems appropriate*, including other factors *it deems relevant* to the determination. This (non-)standard provides regulated parties no "reasonable opportunity to know what is prohibited, so that [they] may act accordingly." *Grayned*, 408 U.S. at 108. Rather, regulated parties—after selling tens of thousands of products for many years—must wait for the Commission to decide *post hoc* which "relevant" or "appropriate" factors will be used to determine the safety of a product.

Such a regime is even more egregious here because the CPSA threatens criminal sanctions. *See* 15 U.S.C. § 2070. And "[w]here a penal statute could sweep so broadly as to render criminal a host of what might otherwise be considered ordinary activities, [the Supreme Court] ha[s] been wary about going beyond what Congress certainly intended the statute to cover." *Sackett*, 598 U.S. at 681 (quotation and citation omitted); *see also WEC Carolina Energy Sols. LLC v. Miller*, 687 F.3d 199, 204 (4th Cir. 2012) ("Where ... our analysis involves a statute whose provisions have both civil and criminal application, our task merits special attention because our interpretation applies uniformly in both contexts. ... Thus, we follow 'the canon of strict construction of criminal statutes, or rule of lenity.'" (citations omitted)). Complaint Counsel's view thus "gives rise to serious vagueness concerns in light of the [CPSA's] criminal penalties," thus implicating the due process requirement that penal statutes be defined "with

sufficient definiteness that ordinary people can understand what conduct is prohibited." *Sackett*, 598 U.S. at 680 (cleaned up).

At bottom, under Complaint Counsel's view, neither the statute nor the Commission's regulation provides Leachco with the "fair notice" required by our Constitution. *See FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 ("A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required.") (citing *Connally v. General Constr. Co.*, 269 U.S. 385, 391 (1926) ("A statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law.").[101] Because parties regulated under the CPSA cannot "steer between lawful and unlawful conduct," the statute is void for vagueness. *Grayned*, 408 U.S. at 108.

IV. CPSC'S OBJECTIONS TO PRESIDING OFFICER'S EVIDENTIARY DECISIONS LACK MERIT.

A. The Presiding Officer properly excluded testimony outside of Dr. Katwa's area of expertise.

Dr. Katwa is a pulmonologist specializing in the "evaluation and treatment of infants and children with sleep apnea and other sleep and breathing disorders." CCX-3, p. 5. His scholarship reveals experience in sleep and breathing disorders; he has authored articles such as "MRI findings and sleep apnea in children with Chiari I malformation;" "Restless legs syndrome and periodic limb movement disorders in pediatric population;" and "Sleep endoscopy-directed management of Arnold-Chiari malformation: a child with

[101] *Cf. Sackett*, 598 U.S. at 689 ("[M]ost laws do not require the hiring of expert consultants to determine if they even apply to you or your property.").

persistent obstructive sleep apnea." *Id.*, Ex. A, pp. 14–16. His opinions on those topics were *not* excluded.

But Complaint Counsel protests that its "medical" expert was precluded from offering opinions on *non*-medical subjects. CPSC Br. 23–25. This argument fails because the opinion of an expert is not admissible unless it has a "reliable basis in the knowledge and experience of *his discipline*." *Daubert*, 509 U.S. at 592 (emphasis added). Opinions on issues outside a witness's expertise lack "the requisite scientific knowledge for his testimony to be helpful to the" trier of fact—and must be excluded. *Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 615 (7th Cir. 1993).

A proffered expert witness must have specialized knowledge on matters relevant to the case. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999); *Tanner v. Westbrook*, 174 F.3d 542, 548 (5th Cir. 1999). Therefore, even if a witness has some special knowledge or experience, the "qualification to testify as an expert also requires that the area of the witness's competence matches the subject matter of the witness's testimony." *Bryant v. 3M Co.*, 78 F.Supp.3d 626, 632 (S.D. Miss. 2015) (quoting 29 Charles A. Wright, Arthur R. Miller, & Victor J. Gold, Federal Practice and Procedure § 6265 (1st ed. 2014)).

According to Complaint Counsel, however, Dr. Katwa's opinions on non-medical topics like design, consumer behavior, infant movement (*not* in a Podster), and marketing disinformation should have been admitted. CPSC Br. 24–25. First, Complaint Counsel claims Dr. Katwa's testimony on these topics is based on the opinions of Mannen and Kish. *Id.* 24. But a non-expert (in a certain field) cannot simply bootstrap the (supposedly) expert opinions of others.

Therefore, Dr. Katwa's attempted "me-too" expert opinions were properly excluded.

Complaint Counsel also argues that Dr. Katwa's opinions on topics like design were based on his expertise. CPSC Br. 24 (citing CCX-3, pp. 5, 36–54). Here, Complaint Counsel cites Dr. Katwa's three-paragraph statement of his "qualifications and expertise" (CCX-3, p. 5) and his CV (*id*. at pp. 36–54). But neither of these sources says anything about design, consumer behavior, etc. Complaint Counsel's bare assertion that Dr. Katwa's experience—in infant pulmonology—authorizes his testimony on any potentially related topic is deficient as a matter of law. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"—much less by the *ipse dixit* of counsel. *Gen. Elec. Co.*, 522 U.S. at 146.

Complaint Counsel also mischaracterizes the Presiding Officer's order that excluded portions of Dr. Katwa's testimony. For example, to support its claim that the Presiding Officer excluded relevant testimony, Complaint Counsel points to, among others, pages 7 and 15 of Katwa's report. *See* CPSC Br. 24 n.34. But those pages were *not* excluded; they are part of Dr. Katwa's discussion of "Background Regarding Infant Physiology, Breathing, and Sleep"—a discussion within Dr. Katwa's area of expertise. CCX-3, pp. 5–17.

Complaint Counsel's attempt to use Leachco's cross-examination of Dr. Katwa also fails. CPSC Br. 25. During cross-examination, Dr. Katwa admitted that his opinions concerning potential risks to infant breathing depended on what happens in a Podster. *Id*. n.35. Thus, as Dr. Katwa later admitted, the potential risks to infants that he discussed on pages 6–17 of his report apply to

all infants *in any environment*—not just in a Podster. Tr. 3, 8:15–9:6. This testimony confirms that Dr. Katwa's medical opinions would not be relevant unless and until Complaint Counsel could demonstrate that infants in a Podster will face the purported risks. That is, Dr. Katwa's opinions concerning, *e.g.*, how an infant's neck position may affect an infant's breathing (CCX-3, p. 10), are not relevant unless Complaint Counsel could demonstrate in fact that infants' necks will likely be in a compromised position. Because that evidence was lacking, Dr. Katwa's medical opinions were irrelevant.

Finally, Complaint Counsel claims that Dr. Katwa's discussion of "Marketing Disinformation" (CCX-3, pp. 29–30) wasn't really about marketing disinformation. CPSC Br. 25.[102] His report contradicts this claim. For example, Dr. Katwa asserts that Leachco's marketing "can cause caregivers to forego seeking the advice of such medical professionals, and, instead, buy these products to help with baby breathing or reflux symptoms." CCX-3, p. 29. Dr. Katwa similarly opines that the Podster is a "dangerous" product. *Id*. These are not medical opinions, and Dr. Katwa has no expertise on how—if at all—consumers might respond to marketing on product safety.

B. The Presiding Officer properly excluded evidence and testimony that Complaint Counsel failed to disclose during discovery.

1. The Presiding Officer properly excluded Kish's testimony about warnings.

The Presiding Officer, after excluding Ms. Kish's testimony about warnings, did consider it: "Kish's assertions about the defective warnings *have been considered* in addressing the Commission's allegations that the propensity

[102] As discussed below, evidence and opinions related to warnings, marketing, etc., were properly excluded because Complaint Counsel admitted that Leachco's warnings had nothing to do with this case.

for misuse of the Podster, which includes the inadequacy of warnings as a deterrent to such misuse, contributes to the alleged design defect." Initial Decision 39 n.26 (emphasis added). This analysis is precisely the reason Complaint Counsel wanted Kish's testimony considered. But the Presiding Officer found the evidence insufficient. Complaint Counsel's argument (CPSC Br. 25–28) here is without basis. Nonetheless, the evidence was properly excluded.

Complaint Counsel asks to be rewarded for hiding the ball throughout the pre-hearing process. In its Complaint, Complaint Counsel alleged that the Podster was a substantial product hazard—despite its warnings and instructions. *See* Compl., ¶¶20, 23, 38. But Complaint Counsel did *not* allege that the Podster was a substantial product hazard because of defective warnings.[103] And, during discovery, Complaint Counsel consistently objected to requests for information about warnings on the ground that Leachco was seeking "information outside the permissible scope of discovery set forth in 16 C.F.R. § 1025.31(c)" and was "not reasonably calculated to lead to the discovery of admissible evidence pertaining to the issue involved in these proceedings—namely, whether Respondent's Podsters are defective and create a substantial product hazard …." *See* Leachco's Motion for Summary Decision, Dkt. 91, p. 27 (quoting CPSC Initial Resp. to ROG No. 5). Again, according to Complaint Counsel, the "issue in this matter is whether the Podsters present a substantial product hazard, not whether a product with modified warnings or instructions would pose a hazard." *Id*. Complaint Counsel confirmed that it was "not making contentions about any 'warning or instruction'" that Leachco "provided

[103] By "warnings," Leachco refers to warnings, instructions, and marketing materials.

improperly or failed to provide in connection with the Podster." *Id*. (quoting CPSC First Supp. Resp. to ROG No. 5).

After the close of fact discovery—March 20, 2023[104]—Complaint Counsel changed its story. First, Complaint Counsel proffered the testimony of its long-time employee Ms. Kish, who spent the majority of her report discussing the Podster's warnings. CCX-2 (May 2, 2023). Second—even later (May 11, 2023)—Complaint Counsel served a fourth supplemental response to Leachco's interrogatories and stated that "information regarding the insufficiency of the Podster's warnings" was set forth in Kish's testimony. *See* Dkt. 91, pp. 27–28.[105]

As a result of Complaint Counsel's unwavering representations that warnings were irrelevant to this case, the Presiding Officer properly excluded Complaint Counsel's untimely disclosure and arguments concerning the Podster's warnings.[106]

In its appeal brief, Complaint Counsel completely ignores its consistent representations that information related to warnings was "not reasonably calculated to lead to the discovery of admissible evidence pertaining to the issue involved in these proceedings …." Instead, Complaint Counsel changes the subject, now arguing that the efficacy of the Podster's warnings *is* relevant to the analysis in the Commission's non-binding regulation. 16 C.F.R. § 1115.4. If

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[104] Order on Prehearing Schedule, Dkt. No. 35 (Sept. 16, 2022).

[105] Yet, even later, Complaint Counsel still argued that arguments about the Podster's warnings were "irrelevant" because they relate to "what Complaint Counsel is *not* alleging." *See* CPSC Resp. to Leachco Mtn. S.D., Dkt. 95, p. 17 n.48 (June 23, 2023) (emphasis in original).

[106] *See* Order Granting in Part and Denying in Part Respondent's Motion to Exclude the Expert Testimony Proffered by the Consumer Product Safety Commission, Dkt. No. 128, pp. 3–5 (Aug. 2, 2023) (*Daubert* Order); Order Granting in Part and Denying in Part Leachco, Inc.'s Motion in Limine to Exclude (1) All Post-Fact-Discovery Evidence & (2) Testimony & Documents Regarding Alleged Defects in the Podster's Warnings, Dkt. No. 129 (Aug. 2, 2023) (*Limine* Order).

so, however, Complaint Counsel misled the Presiding Officer and Leachco by claiming the opposite throughout the case.

Further, Complaint Counsel falsely states that it did allege the inadequacy of the warnings. CPSC Br. 27 (citing Compl., ¶20). Not so. Paragraph 20 of the Complaint alleges potential consumer misuse "*[d]espite* the warnings and instruction," and "*even if* the caregiver is aware of the contrary product warnings," or because consumers "may disregard or not fully read the Podsters' warnings." Compl., ¶20 (emphasis added). Nowhere does Complaint Counsel allege that the Podster's warnings are deficient. Rather, the Complaint alleges, among other things, that, the Podster "contains warnings" that it "should not be used for sleep and that adult supervision is always required," that it "should only be used on the floor, and not in another product, such as a crib, on a bed, table, playpen, counter, or any elevated surface," and that "use of the product in contravention to these warnings could result in serious injury or death." *See* Compl., ¶¶15–19.

Complaint Counsel complains that the Presiding Officer held that it (Complaint Counsel) hadn't alleged a defective-warning claim when the issue was whether the Podster's warnings were insufficient. CPSC Br. 27. Complaint Counsel is not being forthright. The Presiding Officer's analysis was not limited to Complaint Counsel's failure to allege a defective-warning claim. He also noted that Complaint Counsel repeatedly represented that it was not making any contentions about the Podster's warnings. *Daubert* Order, Dkt. 128, p. 3 (quoting Complaint Counsel's discovery responses). And the Presiding Officer expressly rejected Complaint Counsel's belated reliance on an "inadequacy" rationale. *Id.* at 3–4; *see also id.* at 4 (noting that Complaint Counsel

"consistently objected to discovery based on irrelevancy of *such associated information*") (emphasis added). Complaint Counsel's only response is to point to the very evidence that is in dispute—evidence concerning the Podster's warnings. CSPC. Br. 27.

Separately, even if Complaint Counsel had in fact claimed the relevancy of warnings all along, Ms. Kish's testimony proves that it's irrelevant. As the Presiding Officer observed, Ms. Kish herself opined that *no warnings* would make the Podster safe. Initial Decision 50. Indeed, "[b]ecause Complaint Counsel must effectively concede that additional or improved warnings would have been useless, based on [its] own expert's opinion on the matter, the absence of warnings is also a non-factor in the defect analysis." *Id*. The issue is wholly irrelevant.[107] Complaint Counsel's after-the-fact misrepresentations can't save it from its own expert's conclusions.

Finally, Complaint Counsel's argument to the contrary (CPSC Br. 25–28) does not withstand scrutiny. The argument is that Ms. Kish's "warnings" testimony is relevant to Complaint Counsel's claim that the Podster has a design defect. *See id*. (citing 16 C.F.R. § 1115.4). But, as shown above, Complaint Counsel itself repeatedly and consistently denied that anything to do with warnings was *not* relevant. The argument presented in Complaint Counsel's appellate brief directly contradicts Complaint Counsel's prehearing representations and arguments.

[107] If anything, the evidence supports Leachco since Complaint Counsel does not allege a single injury associated with the proper—instructed—use of the Podster. Complaint Counsel's speculation about the deficiency of the Podster's warnings is just that, speculation. Ultimately, Complaint Counsel cannot show that many or most consumers failed or would fail to heed the Podsters warnings.

Complaint Counsel cannot belatedly change its theory of the case—after discovery closes. The Presiding Officer's order excluding evidence about the alleged deficiency of Leachco's warnings was proper. Parties cannot "explicitly refute[] th[e] theory of" their case "only to adopt it a few[] short months later" after discovery has closed. *Aetna Inc. v. Mednax, Inc.*, No. 18-cv-2217, 2021 WL 949454, at *6 (E.D. Pa. Mar. 12, 2021). If a party "knew it would announce its pursuit" of a new theory "in an expert report," then failure to "disclose this ... theory seems willful," and a party cannot "refute[]" the theory "during fact discovery" only for the expert to "adopt[]" the theory "shortly thereafter." *Id.* at *6 n.7. And a failure to properly reveal legal theories before expert discovery is cause for excluding expert testimony. *MLC Intellectual Prop., LLC v. Micron Technology*, 10 F.4th 1358, 1371 (2021); *see also Igenco Holdings, LLC v. Ace Am. Ins. Co.*, 921 F.3d 803, 821–22 (9th Cir. 2019) (excluding damages theory introduced through expert who had not been previously disclosed); *Elliott v. Google, Inc.*, 860 F.3d 1151, 1161 (9th Cir. 2017) (excluding evidence of a theory offered by a party where it was "not disclosed during discovery").

Parties cannot be forced to "glean[] ... theories" from vague statements; the theory must be clear. *Masimo Corp. v. Apple, Inc.*, No. SACV2000048JVSJDEX, 2022 WL 18285029, at *7 (C.D. Cal. Nov. 22, 2022). And when a party does not "provide notice for the basis of" an expert's opinion, "[o]ffering additional fact-question time during the relevant expert depositions would be insufficient." *Id.* After all, parties cannot "explicitly refute[] th[e] theory of" the case "only to adopt it a few[] short months later" after discovery has closed. *Aetna*, 2021 WL 949454, at *6. If a party "knew it would announce its pursuit" of a new theory "in an expert report," then failure to "disclose this ...

theory seems willful," and a party cannot "refute[]" the theory "during fact discovery" only for the expert to "adop[t]" the theory "shortly thereafter." *Id.* at *6 n.7.

2. The Presiding Officer properly excluded Konica McMullen from testifying.

Again Complaint Counsel asks to be rewarded for its pretrial gamesmanship. CPSC Br. 29–32. In Leachco's first set of interrogatories, served March 14, 2022, Leachco asked Complaint Counsel to "[i]dentify any Person who was a witness to or has knowledge of the facts, circumstances and events that are related to the relief requested in the Complaint, or who otherwise has knowledge relevant to the issues in this case …." Not until May 11, 2023—15 months after this case was filed and almost two months after fact discovery closed, in its *fourth supplemental* responses—did Complaint Counsel identify Konica McMullen in response to Leachco's interrogatory. *See* Leachco Mtn. to Strike Konica McMullen from Commission's Witness List, Dkt. 119, pp. 2–3.

Nor can Complaint Counsel claim it wasn't aware of Ms. McMullen even before this case started. It had known about her for over five years before this proceeding was even started. *See* JX-6 (IDI for Alabama Incident). Pursuant to the Commission's rules, the Presiding Officer may "take such action as is just, including but not limited to the following: ... Order that the party withholding discovery not introduce into evidence or otherwise rely, in support of any claim or defense, upon the documents or other evidence withheld." 16 C.F.R. § 1025.37(c)); *see also* Fed. R. Civ. P. 37(c)(1) ("If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is

harmless."). Here, Complaint Counsel has no excuse for failing to disclose Ms. McMullen until after the close of all discovery.

This failure was far from harmless. Leachco was precluded from deposing Ms. McMullen. Although Complaint Counsel claims that Leachco did depose her (CPSC Br. 30), that deposition took place in a separate, private lawsuit, which involved—as Complaint Counsel elsewhere emphasizes—different issues. Indeed, Complaint Counsel repeatedly argues that it need not show any injuries to establish a substantial product hazard under the CPSA. Therefore, it apparently thought they didn't need to call Ms. McMullen as a witness. Whether that's true or not, Complaint Counsel made a strategic decision not to identify her. It can't now complain that its bluff was called.

Ultimately, the Presiding Officer excluded Ms. McMullen for a slightly different reason.[108] But his decision may be upheld on any lawful ground. *Cf. United States v. Holmes*, 727 F.3d 1230, 1233 (10th Cir. 2013) (Appellate courts

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[108] The Presiding Officer concluded that Leachco wasn't prejudiced because it was aware of Ms. McMullen's existence and the testimony she could offer. *See* McMullen Order, Dkt. 125, p. 3. But Leachco was aware of numerous potential witnesses and their testimony. If that were the proper standard, then parties could routinely withhold the identity of trial witnesses until the eve of trial. Late disclosure prejudices parties who must decide how to use limited resources to prepare for trial. Because Complaint Counsel did not identify Ms. McMullen—even as someone with knowledge of the case—Leachco did not depose her. That prejudice alone is sufficient to have precluded her from being called at the hearing: "Prejudice generally occurs when late disclosure deprives the opposing party of a meaningful opportunity to perform discovery and depositions related to the documents or witnesses in question." *Bowe v. Pub. Storage*, 106 F.Supp.3d 1252, 1260 (S.D. Fla. 2015) (citation omitted); *see also Ollier v. Sweetwater Union High Sch. Dist.*, 768 F.3d 843, 862 (9th Cir. 2014) (upholding district court order excluding 30 witnesses identified after fact discovery closed and ten months before trial); *Pete's Towing Co. v. City of Tampa*, 378 F. App'x 917, 920 (11th Cir. 2010) (upholding exclusion of testimony where plaintiffs filed late); *Medina v. Multaler, Inc.*, 547 F.Supp.2d 1099, 1105 n.8 (C.D. Cal. 2007) ("Medina's failure to disclose Hannaway as a likely witness before defendants' summary judgment motion was filed prejudiced defendants by depriving them of an opportunity to depose him."); *Lil' Man in the Boat, Inc. v. City and Cnty. of San Francisco*, No. 17-cv-00904-JST, 2019 WL 8263440, at *4 (N.D. Cal. Nov. 26, 2019) (excluding witness testimony where "[d]efendants were deprived of the opportunity to take [the witness's] deposition before the close of discovery and were forced to confront his testimony for the first time on summary judgment").

generally "may affirm a district court judgment on a basis different from that employed by the district court, assuming that the alternate basis is consistent with the record."). According to the Presiding Officer, Ms. McMullen's testimony was excluded because she lacked first-hand knowledge about the Alabama Incident (which took place after she left her son at daycare) or the Podster (which she did not purchase or use). Ms. McMullen's testimony was not probative of the issues before the court—the (allegedly) reasonably foreseeable misuse of the Podster and the risk of injury created by an alleged defect. *See* Order, Dkt. 125, pp. 3–4. Therefore, the Presiding Officer noted, only "unexpected" testimony from Ms. McMullen could be relevant and, *unexpected* testimony *would* unfairly prejudice Leachco. *Id*. at 4.

Here, Complaint Counsel appears to suggest that Ms. McMullen could have offered quasi-expert testimony, *i.e.*, "how an otherwise healthy infant with certain mobility capacities can suffocate within a Podster." CPSC Br. 31. Complaint Counsel nowhere provided the foundation to demonstrate that Ms. McMullen could competently testify on that topic. As the Presiding Officer noted, Complaint Counsel objected to Leachco's discovery requests concerning the health of infants involved in the incidents. *See* Order, Dkt. 131, pp. 1–2. And, in any event, the Presiding Officer properly rejected Complaint Counsel's vague suggestion that Ms. McMullen would testify "about the victim." Order, Dkt. 125, p. 4.

Finally, Complaint Counsel claims it was irrational for the Presiding Officer to exclude evidence on (in part) prejudice grounds since this was a bench trial. CPSC Br. 31. Nothing Complaint Counsel cites, however, requires a judge in a bench trial to consider (ostensibly) probative evidence if it's prejudicial. And,

as already noted, the Presiding Officer concluded that Ms. McMullen's testimony was *not* probative. The order excluding her testimony was well within the Presiding Officer's discretion and should be affirmed.

C. The Presiding Officer properly excluded hearsay evidence.

Complaint Counsel argues that JX-12A and JX-12B should have been admitted in their entirety under the public-records exception to the hearsay rule. CPSC Br. 28–29. But, as the Presiding Officer correctly noted, while some documents in these exhibits are admissible, many of the documents are hearsay that do not qualify for admission under any exception. Complaint Counsel's argument fails.

The public-records exception allows the introduction of a hearsay statement if "it sets out" the "factual findings from a legally authorized investigation." Fed. R. Evid. 803(8)(A)(iii). This hearsay exception does not allow the admission of every statement just because it appears in a public record. Only things like investigative observations, laboratory test results, or statistical analysis are admissible under this exception. *C.O. v. Coleman Co.*, No. 06-cv-1779, 2008 WL 820066, at *2 n.6 (W.D. Wash. Mar. 25, 2008). It does not allow government investigators to "rely upon, and merely reproduce, second- or third-hand knowledge of previous events." *Id.*

Indeed, third-party statements—even if included in a public record—are themselves hearsay. *See United States v. Moore*, 27 F.3d 969, 975 (4th Cir. 1994). Accordingly, "statements by third parties who are not government employees (or otherwise under a legal duty to report) may not be admitted pursuant to the public records exception," *United States v. Morales*, 720 F.3d 1194, 1202 (9th Cir. 2013), unless they fall within another hearsay exception. *United States v.*

Mackey, 117 F.3d 24, 29 (1st Cir. 1997). The Presiding Officer therefore properly excluded those portions of IDIs that "contain circumstances reported by third parties and third-party notes." CPSC Br. 28 (quoting Presiding Officer Order, Dkt. 127).

Complaint Counsel has not identified any hearsay exception that would allow the third-party statements contained within its JX-12A and JX-12B to be admissible. Accordingly, pages 1–2 (the Medical Examiner Report of Investigation) and pages 3–5 (the Autopsy Report) of these exhibits are admissible. The remaining statements in these exhibits contain third-party statements for which no hearsay exception applies. They were properly excluded.

CONCLUSION

The Presiding Officer's Initial Decision should be affirmed.

DATED: October 17, 2024.

Respectfully submitted,

/s/ Oliver J. Dunford

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I hereby certify that on October 17, 2024, the foregoing was served via email on the following:

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No. 22-1

Consumer Product Safety Commission

IN THE MATTER OF LEACHCO, INC.

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

RESPONDENT LEACHCO'S OPENING BRIEF IN SUPPORT OF CROSS-APPEAL

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

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BRIEF IN SUPPORT OF LEACHCO'S CROSS-APPEAL

The Presiding Officer correctly held that the Podster is not a substantial product hazard under the Consumer Product Safety Act. The Presiding Officer concluded that the Podster was not (1) a product defect (2) that creates (3) a substantial risk of injury to the public. Initial Decision 65; 15 U.S.C. § 2064(a)(2). That decision should be affirmed for all the reasons set forth in Leachco's Answering Brief. Rather than repeating the factual and procedural background from its Answering Brief, Leachco incorporates its Answering Brief here and adds the following summary of the background related to this Cross-Appeal Brief.

Complaint Counsel filed its administrative complaint in February 2022, after which Leachco and Complaint Counsel engaged in significant discovery, filed various discovery and pre-trial motions, and faced off in an administrative hearing before Administrative Law Judge Michael G. Young, appointed as the Commission's Presiding Officer. The hearing was conducted August 7–10, 2023, in the Commission's Bethesda, Maryland, offices.

Complaint Counsel, among other things, submitted the testimony of three proffered expert witnesses: Erin M. Mannen, Ph.D.; Celestine Kish; and Umakanth Katwa, M.B.B.S., M.D. 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."[1] Celestine Kish, a 34-year employee of the CPSC,[2] opined that consumers' observations of other

[1] CCX-1 (Mannen Report), p. 5.
[2] CCX-2 (Kish Report), p. 2.

consumers' misuse can encourage misuse and that it is foreseeable that consumers will use the Podster in a dangerous manner.[3] Dr. Katwa testified generally about the physiology of infant breathing.[4]

Before the hearing, as detailed below, the Presiding Officer granted in part and denied in part Leachco's *Daubert* Motion (Dkt. Nos. 114, 115) and its Motion *in Limine* (Dkt. Nos. 116, 117). In his orders, the Presiding Officer (1) excluded expert testimony concerning the Podster's warnings, *see* Order, Dkt. 128, pp. 3–5; Order, Dkt. 129, pp. 2,[5] (2) excluded the testimony of Dr. Katwa that was beyond the scope of his medical expertise (the Podster's design, alleged use of the Podster, and alleged defective marketing), *see* Order, Dkt. 128, at 6–7. Therefore, the expert reports of Ms. Kish and Dr. Katwa were admitted subject to those orders. Under the Commission's rules, expert witnesses are not deposed before administrative hearings, 16 C.F.R. § 1025.44(b), and so Leachco did not have the opportunity to cross-examine Complaint Counsel's proffered experts until the hearing.

Here, Leachco submits that, notwithstanding the Presiding Officer's conclusion in his Initial Decision and for the purposes of preserving issues, the Presiding Officer erred in admitting certain evidence and that the Commission's administrative hearing violated Leachco's constitutional rights. A ruling Leachco's favor here would only confirm that Complaint Counsel failed to prove its claim that the Podster is a substantial product hazard under the CPSA. And

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[3] CCX-2, pp. 1–2.

[4] CCX-3 (Katwa Report), pp. 5–17.

[5] Order Granting in Part and Denying Part Respondent's Motion to Exclude the Expert Testimony Proffered by the Consumer Product Safety Commission, Dkt. 128 (Aug. 2, 2023); Order Granting in Part and Denying in Part Leachco, Inc.'s Motion in Limine to Exclude (1) All Post-Fact-Discovery Evidence & (2) Testimony & Documents Regarding Alleged Defects in the Podster's Warnings, Dkt. 129 (Aug. 2, 2023).

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

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

Initial Decision 65.

STATEMENT OF REASONS THE INITIAL DECISION IS, IN PART, INCORRECT

Pursuant to 16 C.F.R. § 1025.53(b)(3), and as detailed below, Leachco identifies the following "reasons why [it] believes the Initial Decision is incorrect":

1. The Presiding Officer erred by not striking Complaint Counsel's expert testimony in its entirety.

2. The Presiding Officer erred by admitting hearsay.

3. The Commission's administrative hearings violated Leachco's right to due process of law.

4. The Commission's administrative hearings violated Leachco's rights under Article II of the Constitution, the Constitution's Separation of Powers, Article III, the Fifth Amendment's right to due process of law, and the Seventh Amendment's right to a jury trial.

ARGUMENT

I. THE PRESIDING OFFICER ERRED BY NOT STRIKING CPSC'S EXPERT TESTIMONY IN ITS ENTIRETY.[6]

The Presiding Officer properly excluded expert testimony concerning the Podster's warnings. *See* Order, Dkt. 128, pp. 3–5; Order, Dkt. 129, p. 2. And he

[6] Leachco incorporates its Motion for Summary Decision (Dkt. 91); its *Daubert* Motion and Memorandum in Support (Dkt. Nos. 114, 115); its Motion *in Limine* and Memorandum in Support (Dkt. Nos. 116, 117); its Response in Opposition to the Commission's Motion *in Limine* to Admit In-Depth Investigation Reports (Dkt. 124); and its Post-Hearing Brief (Dkt. 144).

properly excluded the part of Dr. Katwa's testimony that was beyond the scope of his medical expertise. *See* Order, Dkt. 128, pp. 6–7.

The Presiding Officer also correctly observed material deficiencies in the testimonies offered by Dr. Mannen and Ms. Kish, but he nonetheless overruled Leachco's arguments that their testimony—along with Dr. Katwa's testimony—should have been entirely stricken. Initial Decision 57–58; Order, Dkt. 128, pp. 5–6. This was error. Judges are required to act as "gatekeepers" to prevent unqualified witnesses from presenting unreliable or irrelevant evidence. In that role, judges must 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). This gatekeeping role "inherently requires the trial court to conduct an exacting analysis of the foundations of expert opinions to ensure they meet the standards for admissibility under Rule 702." *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (cleaned up).

Critically, 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., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

Here, Dr. Mannen and Ms. Kish's opinions should have been stricken in their entirety because they are not the product of reliable scientific methods, and they were not—and could not be—objectively validated as accurately reflecting (1) live infants in a Podster (Mannen) or (2) individuals' on-line practices and reactions to media generally (Kish). *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 n.11 (9th Cir. 1995) (*Daubert II*) ("[T]he party

proffering the evidence must explain the expert's methodology and demonstrate in some objectively verifiable way that the expert has both chosen a reliable scientific method and followed it faithfully."); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

Further, Dr. Katwa's general opinions about infant breathing—which he admitted apply to all products and in any circumstance—could be admitted only if Dr. Mannen's and Ms. Kish's opinions were first found to satisfy Federal Rule of Evidence 702. Because the latter opinions failed to meet the requirements of Rule 702, they should have been stricken in their entirety; and, as a result, Dr. Katwa's opinions should have been stricken as irrelevant to this case.

A. Standard of Admissibility

The admission of expert testimony is an exception from the norm that all evidence must be based on first-hand knowledge. 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*, 509 U.S. at 597. And 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*, 526 U.S. at 152.

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."[7] 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. In sum, the witness must be qualified, the testimony must help the trier of fact, and the testimony must be reliable.

As the Supreme Court held, "the Rules of Evidence—especially Rule 702—do assign to the trial judge the task of ensuring that an expert's testimony … rests on a reliable foundation." *Daubert*, 509 U.S. at 597. When evaluating the reliability of scientific expert opinion, the judge must assess "whether the reasoning or methodology underlying the testimony is scientifically valid and ... whether that reasoning or methodology properly can be applied to the facts in issue." *Id*. at 592–93. Whether an expert's testimony is reliable depends on "the particular facts and circumstances of the particular case." *Kumho Tire*, 526 U.S. at 158. To determine if an expert's methodology is reliable, courts consider, among other factors, (1) whether the methodology can be and has been tested, (2) whether the theory or technique has been subjected to peer review, (3) the known or potential rate of error of the methodology employed, and (4) whether the methodology is generally accepted. *Daubert*, 509 U.S. at 593–94.

The proponent of an expert witness bears the burden by a preponderance of the evidence showing 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

[7] *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.").

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).

Here, Complaint Counsel's proffered expert testimony should have been stricken in its entirety.

B. Dr. Mannen's testimony should have been stricken in its entirety.

1. Dr. Mannen's testimony should have been stricken in its entirety because none of the methodologies she employed has been peer-reviewed and none has been validated to ensure that the measurements accurately reflect infants' interactions with the Podster.

Dr. Mannen's testimony suffers from two primary flaws: (1) she fails to identify (with one exception that ultimately supports Leachco) any benchmarks or thresholds against which to determine if a defect or risk exists, and, even if she had identified any thresholds, (2) not one method she employed has been peer-reviewed or validated, rendering any "conclusions" hopelessly unreliable.

The inquiry into reliability must focus on "principles and methodology" and not the expert witness's conclusions. *Daubert*, 509 U.S. at 595. While an expert's qualifications may bear on the reliability of her proffered testimony, qualifications alone do not guarantee reliability. *Frazier*, 387 F.3d at 1261 (citing *Quiet Tech. DC–8, Inc. v. Hurel–Dubois UK Ltd.*, 326 F.3d 1333, 1341–42 (11th Cir. 2001)). Because "one may be considered an expert but still offer unreliable testimony," it remains a basic foundation for admissibility under Rule 702 and *Daubert* that proposed expert testimony must be based on "good grounds." *Id.*

As the Presiding Office observed, Dr. Mannen herself "conceded limitations in some of the testing methods and devices she used." Initial Decision

11.

Indeed, Dr. Mannen summarized her six opinions at CCX-1, pp. 5–6, but neither there nor elsewhere in her report (save one exception), did she identify benchmarks or thresholds to determine how and when, if at all, infants might be subjected to a significant risk of injury:

1. Dr. Mannen claims that the Podster's design "[c]auses a flexed head/neck and flexed trunk posture during supine lying, inhibiting normal breathing," CCX-1, p. 6 (footnote omitted), but she never defines "normal" breathing, never states how much flexion is required to inhibit "normal" breathing, and never identifies at what point "normal" breathing is inhibited.

2. Although Dr. Mannen claims that the Podster's design "[f]acilitates some types of rolling on or off of the product, introducing concerning suffocation-related risks for the infant," CCX-1, p. 6, she never says how much the design "facilitates" "some" types of rolling, never defines how "concerning" the alleged risks are, and never identifies at what point the "facilitation" of "some" types of rolling becomes concerning—*i.e.*, at what point this presents a substantial risk of injury to anyone.

3. Although Dr. Manen opines that the Podster's design "[i]ncreases abdominal fatigue if an infant finds themselves [sic] prone in the pillow, increasing the risk of suffocation," CCX-1, p. 6, she never states how much abdominal fatigue is "increased" and never defines the "increasing risk" of suffocation or at what point the "increase" in abdominal fatigue presents a risk of injury (suffocation) to anyone.

4. Although Dr. Mannen claims that the Podster's design "[n]egatively affects the ability of an infant to self-rescue from the prone position to a safe breathing position," CCX-1, p. 6, she never says how much the design negatively affects the ability of an infant to self-rescue.

5. Although Dr. Mannen opines that the Podster's design "[p]ermits an infant in a supine position to move its face into the sides of the Podster where its nose and mouth are obstructed," CCX-1, p. 6, she never identifies how likely such a move is "permitted."

6. Although Dr. Mannen asserts that the Podster's design "negatively affects the ability of an infant to breathe normally if they are [sic] prone or side-facing in the product," CCX-1, p. 6, she again fails to define "normally," and she fails to say how much the design (allegedly) negatively affects an infant's ability to breath "normally."

Instead, her testimony consisted entirely of *comparisons* among various types of products.

Further, nowhere does Dr. Mannen demonstrate that any of the methods she employed or relied on—described below—have been peer-reviewed or validated to show that these test results accurately correlate to results for live infants. *See* Reference Manual on Scientific Evidence 44 (Fed. Jud. Ctr. 3d ed. 2011) ("Peer review works superbly to separate valid science from nonsense …."); *cf. Daubert*, 509 U.S. at 591–92 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."); *see id.* at 590 n.9 ("In a case involving scientific evidence, evidentiary reliability will be based upon scientific validity."). For example, Dr. Mannen relied 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.[8] But none of these studies has been peer-reviewed,[9] and none of the testing methods have been validated.

[8] *See* CCX-1, pp. 8–12 (discussion); 13–14, 16, 21, 23, 25, 29, 32–33, 34, 38, 44, 46, 48–49 (citations).
[9] Tr. 1, 83:22–85:4.

a. Dr. Mannen's Flawed Methodologies

Trunk Flexion

Dr. Mannen opined that the Podster's design causes a flexed neck and flexed trunk posture during supine lying, which inhibits normal breathing.[10] 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.[11]

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

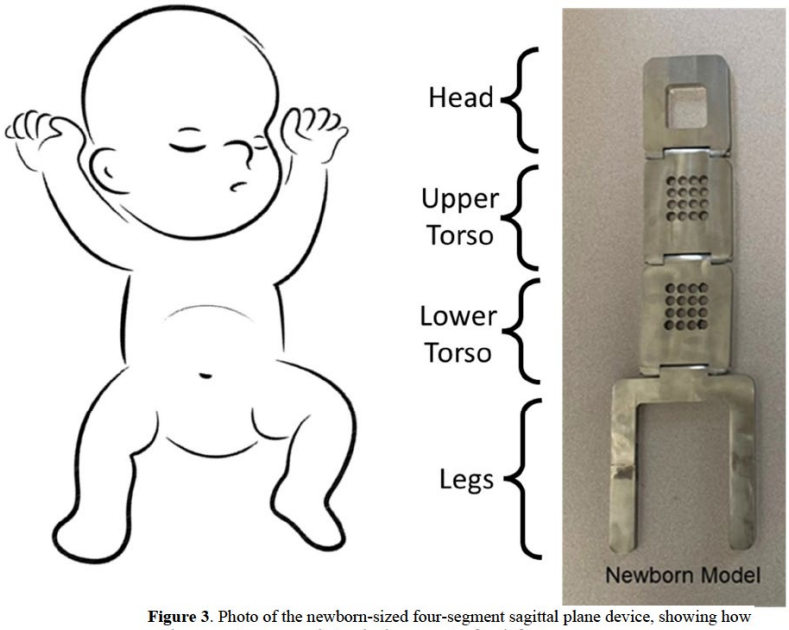

Figure 3. Photo of the newborn-sized four-segment sagittal plane device, showing how each segment corresponds to a body segment of an infant.

[10] CCX-1, p. 6; *see also* Tr. 1, 111:2–8.
[11] CCX-1, pp. 16–18.

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:

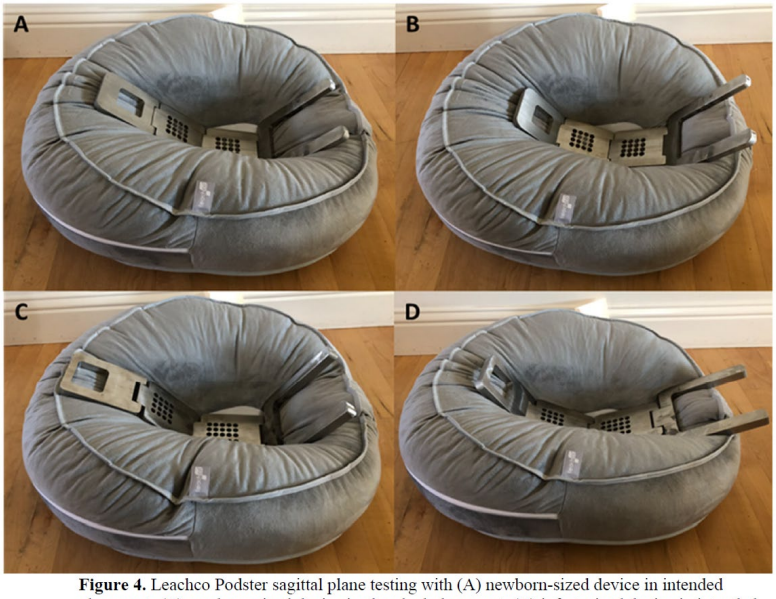

Figure 4. Leachco Podster sagittal plane testing with (A) newborn-sized device in intended placement, (B) newborn-sized device in slouched placement, (C) infant-sized device in intended position, and (D) infant-sized device in slouched position.

Dr. Mannen then measured the angle of the device's "trunk" compared to the angle on a firm, flat mattress.[12] That is, Dr. Mannen measured "the increase in trunk flexion angle compared to the flat crib mattress condition."[13]

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.[14] 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°

[12] *See* CCX-1, pp. 34–35.
[13] CCX-1, p. 35.
[14] CCX-1, p. 35 (Table 1).

compared to a flat mattress.[15] Dr. Mannen and her team created this four-plane sagittal device.[16] 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

To measure neck flexion, Dr. Mannen used newborn- and infant-sized CAMI dolls.[17]

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):

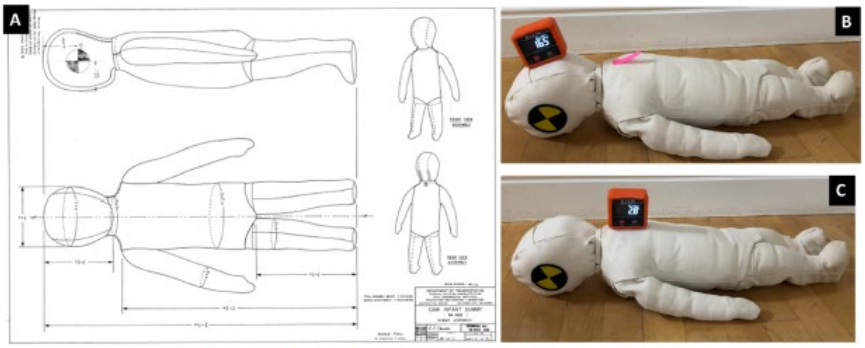

Figure 5. (A) Mechanical drawing and actual photos of the newborn CAMI dummy showing the (B) head angle and (C) torso angle during lying on a firm flat surface.

[15] CCX-1, p. 35 (Table 1).
[16] Tr. 1, 98:13–16.
[17] Tr. 1, 111:22–112:4.

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):

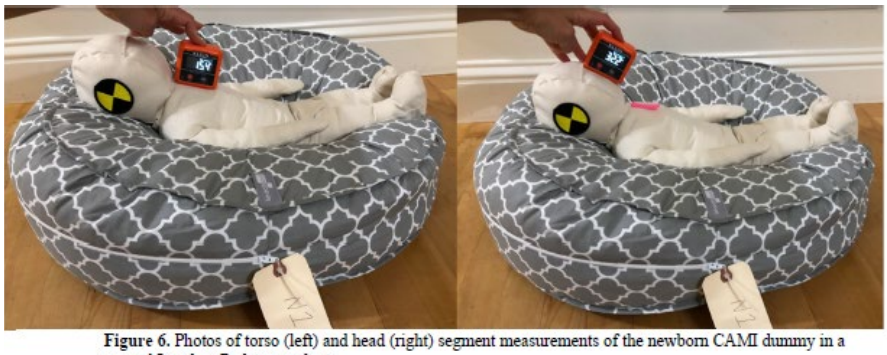

Figure 6. Photos of torso (left) and head (right) segment measurements of the newborn CAMI dummy in a normal Leachco Podster product.

At each placement, Dr. Mannen "calculated the increase in head flexion ... compared to the normalized firm flat surface measurements."[18] 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."[19]

Dr. Mannen acknowledged that a "real baby has trunk flexion."[20] And she admitted that 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."[21]

The results of these comparison measurements were "presented in degrees and … 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.*:

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[18] CCX-1, p. 20.
[19] Tr. 1, 115:12–16.
[20] Tr. 1, 117:10.
[21] Tr. 1, 117:16–118:1.

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

Dr. Mannen had previously used the four-plane sagittal device to test head/neck flexion,[22] but she determined that this device did not accurately measure neck flexion. She thus used CAMI dolls.

But CAMI dolls were designed for crash testing.[23] 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.[24] 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-reviewed study confirming the use of CAMI dolls to accurately measure neck angles.[25] 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

[22] *See* CCX-1, Ex. B (Mannen 2019), Ex. C (Mannen 2022).
[23] Tr. 1, 112:12–15.
[24] 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).
[25] Tr. 1, 113:8–17.

newborn neck angles.[26] Accordingly, Dr. Mannen's expert report, CCX-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.[27]

Dr. Mannen testified that she is unaware of a device that can determine a threshold for safety with respect to neck flexion.[28] She states—her lone threshold—that medical literature says that a neck-flexion angle of 45° is dangerous.[29] She also 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°.[30] Yet Dr. Mannen stated, "but practically does that one degree matter? Probably not."[31]

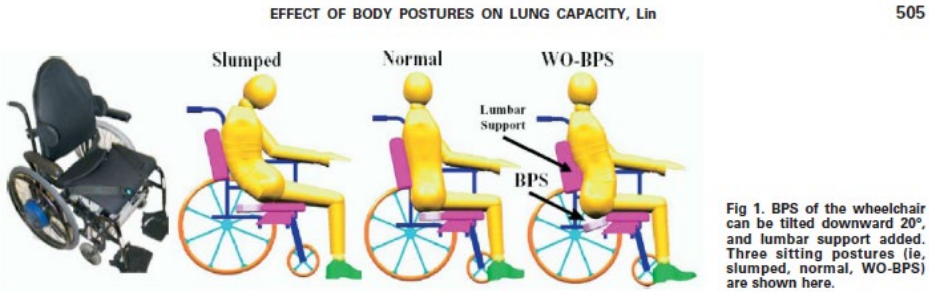
Infant Positioning—Dr. Mannen's Opinion

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."[32] 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."[33] These results, Dr. Mannen opines, have "negative implications" for infant breathing.[34] Dr. Mannen claims, "other researchers have reported that changes in trunk posture can negatively impact pulmonary and respiratory function."[35]

Here, Dr. Mannen cites Lee 2010 and Lin 2006. Dr. Mannen says that Lin 2006 found that a flexed-trunk posture during sitting, "not unlike" an infant's

[26] Tr. 1, 113:18–114:4.
[27] Tr. 1, 114:5–8.
[28] Tr. 1, 110:12–15; 119:2–3.
[29] Tr. 1, 120:10–11; 121:7–16.
[30] Tr. 1, 120:11–15.
[31] Tr. 1, 120:20–22.
[32] CCX-1, pp. 6, 37 (footnote omitted).
[33] CCX-1, p. 38.
[34] CCX-1, p. 38.
[35] CCX-1, p. 39.

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):



These positions of live adults are different from the reclined position (of her sagittal-plane device) that Dr. Mannen tested in the Podster. 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."[36] 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."[37] But, as Dr. Mannen admitted, Lee 2010 did not observe any breathing difficulties.[38]

Dr. Mannen also relies heavily here on Mannen 2019.[39] But the Mannen 2019 study—which tested live infants on inclined sleep products—found no evidence that infants lying supine had oxygen-saturation problems.[40]

[36] RX-31, p. 001.
[37] CCX-1, pp. 39–40.
[38] Tr. 1, 148:20–149:5.
[39] *See* CCX-1, pp. 38–40.
[40] Tr. 1, 111:9–18.

Facilitation of Rolling

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 are obstructed and/or he could experience rebreathing.[41] 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.[42] Dr. Mannen acknowledged, however, that she has never observed an infant lying in a Podster.[43] Dr. Mannen claims that on firm, flat mattresses, "some" types of rolling require first an increase in trunk and hip flexion, followed by rotation.[44] 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."[45]

Dr. Mannen relies on Kobayashi 2016.[46] 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 2016), would not have required the infant to coordinate as many movements to achieve a roll compared to a flat surface."[47] 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."[48] As explained below (pp.

[41] CCX-1, p. 41.
[42] CCX-1, p. 41.
[43] Tr. 1, 126:8–13.
[44] CCX-1, p. 41.
[45] CCX-1, p. 41.
[46] *See* CCX-1, p. 42.
[47] CCX-1, p. 42.
[48] CCX-1, p. 42.

20–21), the latter part of this statement is not accurate. 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.[49]

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.[50] 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.[51] 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 risk, and facilitation of rolling."[52] But she did not observe any infants rolling in any of the inclined sleep products during the Mannen 2019 study.[53]

[49] CCX-1, pp. 42–43.
[50] Tr. 1, 140:3–8.
[51] Tr. 1, 140:12–22.
[52] Tr. 1, 141:15–22.
[53] Tr. 1, 142:1–4.

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

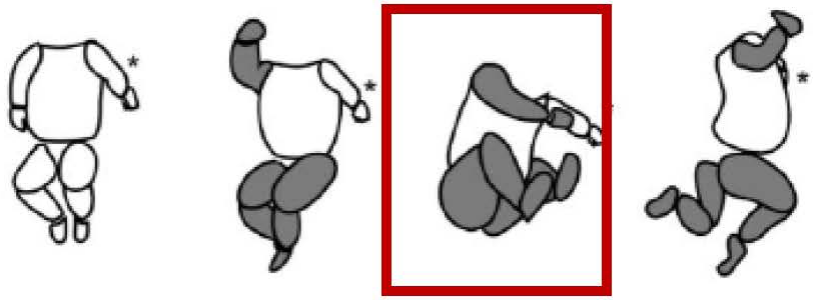


Figure 14. Figure showing a four-step rolling technique (from left to right) which requires coordinated movements where the flexed trunk and flexed hip position (third step, red box) is an intermediate step to complete the rolling task. The Leachco Podster puts an infant in this flexed-hip position,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

Kobayashi 2016 did not study rolling on inclined products; the infants were observed rolling on flat surfaces.[54] Kobayashi 2016 studied two groups of infants: "younger" infants (aged 5–7 months) and "older" infants (8–10 months).[55] The "rolling" figure from Kobayashi 2016 that Dr. Mannen included in her expert report—pattern 8C[56]—is one of six rolling patterns identified by Kobayashi 2016. *See* RX-29, p. 010, as shown here:

[54] *See* RX-29, p. 003.
[55] RX-29, p. 001; Tr. 1, 143:15–19.
[56] CCX-1, p. 42

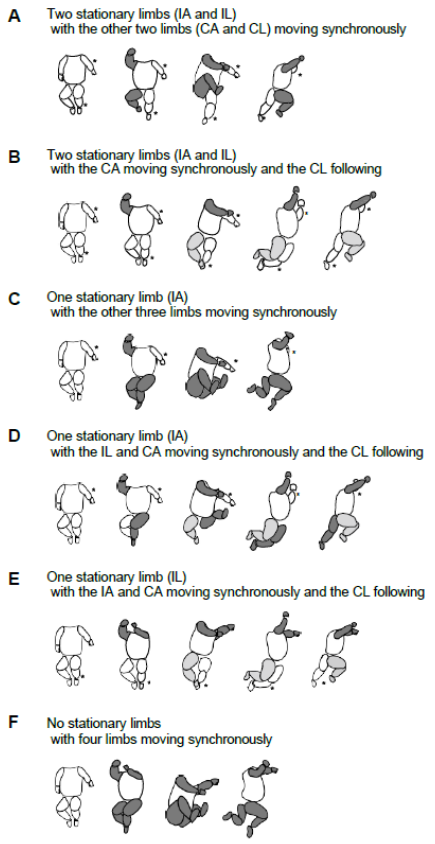


Fig. 8 The serial order of highly observed movement patterns of rolling in infants. Rollings to the *left* are illustrated based on the video data. The limbs indicated with an asterisk are the stationary limbs. The limbs colored *dark gray* represent the synchronous limbs with respect to the movement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

According to Kobayashi 2016, these six patterns are the "highly observed movement patterns of rolling in infants."[57] And the patterns are arranged from most common (8A) to least common (8F).[58] But 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.[59] (That four of the six highly observed rolling patterns do not require the fetal tuck position contradicts Dr. Mannen's statement above (pp. 16–17) that "many" of these movements first require "a

[57] RX-29, p. 010. *See* Tr. 1, 145:1–7.
[58] RX-29, p. 010. *See* Tr. 1, 145:1–7.
[59] RX-29, p. 010. *See* Tr. 1, 145:11–15.

fully or partially flexed trunk and flexed-hip position"). Further, patterns 8C and 8F were most observed among the older infants (aged 8–10 months).[60] 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.[61] And Dr. Mannen acknowledged that the older infants studied in Kobayashi 2016 were too old for the Podster.[62]

Muscle Fatigue and Ability to Self-Rescue

Dr. Mannen opined 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.[63]

Here, Dr. Mannen did not conduct new tests, and she did not observe infants in the Podster. Rather, she relied primarily on Mannen 2019 and two published papers she co-authored: Wang 2020 and Wang 2021. Wang 2020 compared the muscle activity of live infants on inclined-crib mattress (0° vs. 10° v. 20°).[64] Wang 2021 used motion capture and electromyography tools to measure infants in three inclined sleeper products—methods she did not use here.[65] Dr. Mannen nonetheless claims that the results from these papers can be applied to the Podster.[66]

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 ...."[67] According to Dr.

[60] RX-29, pp. 010–011; *see* Tr. 1, 146:15–147:16.
[61] RX-29, p. 011; CCX-1, p. 42; Tr. 1, 147:9–11.
[62] Tr. 1, 144:3–7.
[63] CCX-1, pp. 44–46.
[64] *See* RX-34, p. 001.
[65] *See* RX-35, p. 004.
[66] CCX-1, p. 44.
[67] CCX-1, p. 44.

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."[68]

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 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.'"[69]

Dr. Mannen opines, "when an infant rolls from supine to prone on a Leachco Podster, an infant will experience significant biomechanical challenges."[70] 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."[71] 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

[68] CCX-1, p. 44.
[69] CCX-1, pp. 44–45 (emphasis added).
[70] CCX-1, p. 45.
[71] CCX-1, p. 46.

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."[72]

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*."[73]

Firmness

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.[74]

To measure this (non-)standard, Dr. Mannen developed a "vertical lifter device" that measures vertical displacement at a vertically applied 10 Newton (10N) load.[75] 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."[76] Dr. Mannen used this test method three times on each of the ten Podsters.[77] 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, $p<0.05$).

[72] CCX-1, p. 46.
[73] RX-35, p. 007 (emphasis added).
[74] CCX-1, p. 21.
[75] CCX-1, p. 23.
[76] CCX-1, p. 23.
[77] CCX-1, pp. 23–24.

These values were then compared with displacements measured on the crib mattresses.[78] According to Dr. Mannen, the Podsters failed all tests.[79] 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 an infant's nose and mouth and (b) make it more difficult for an infant to self-rescue."[80] Also, Dr. Mannen states that the Podsters are "significantly softer" than crib mattresses.[81]

Airflow

Dr. Mannen opines that airflow testing can tell how easy it is for air to flow through a product.[82] 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."[83]

Here, 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)."[84] *See id.*, p. 26 (Figure 9):

[78] CCX-1, p. 24.
[79] CCX-1, p. 46.
[80] CCX-1, pp. 46–47.
[81] CCX-1, p. 47.
[82] CCX-1, p. 24.
[83] CCX-1, p. 24.
[84] CCX-1, p. 25.

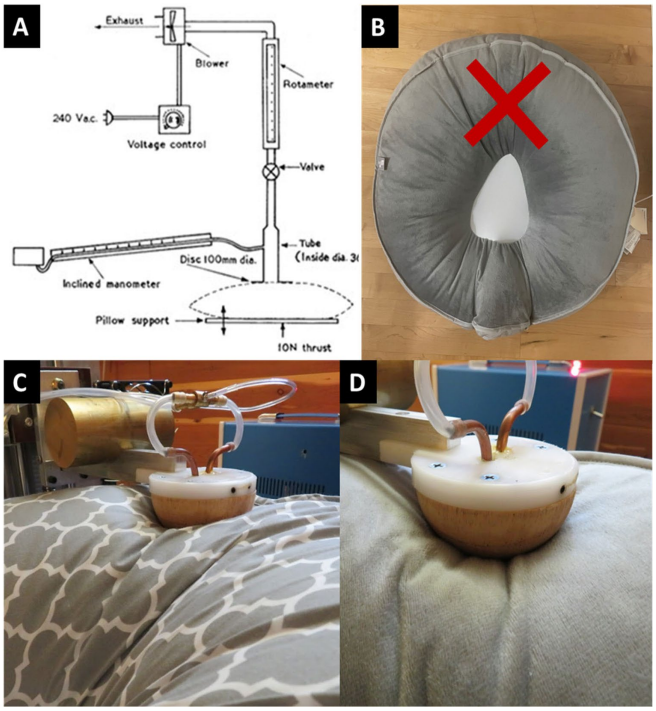


Figure 9. Depiction of (A) airflow testing schematic from BS 4578:1970, and modified test being conducted at (B) the location of intended head placement marked with the red x on (C) a standard Leachco Podster product and (D) a plush Leachco Podster product.

The device does 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."[85] But this was not accounted for in her conclusions.

Dr. Mannen tested the maximum-thickness portion of the ten Podsters three times each.[86] She then calculated means and standard deviations and statistically compared the standard vs. plush results (t-test, $p<0.05$).[87]

Dr. Mannen refers to Mannen 2022, which (Dr. Mannen says) "established that mesh-like airflow represents a condition where air can flow

[85] CCX-1, Ex. C, p. 246.
[86] CCX-1, p. 25.
[87] CCX-1, p. 25.

freely through material."[88] 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."[89]

But neither Mannen 2022 nor Dr. Mannen's expert report here identifies a safety threshold other than based on a comparison of two products.[90]

Mannen 2022 acknowledges the tests significant limitations:

> 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 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.*[91]

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.[92] Dr. Mannen opined that the Podsters "significantly

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[88] CCX-1, p. 25.
[89] CCX-1, Ex. C (Mannen 2022), pp. 215, 221.
[90] *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.").
[91] CCX-1, Ex. C (Mannen 2022), pp. 246–47 (emphasis added).
[92] CCX-1, p. 48.

inhibited normal airflow."[93] And she asserted that "if an infant was breathing into" a Podster, the infant would require "significantly more work to breathe."[94]

Rebreathing

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.[95] At some point—but Dr. Mannen does know where—an infant can "rebreathe[]" "too much" CO_2.[96]

Dr. Mannen tested each of the ten Podsters only one time each and tested a crib mattress with a cotton sheet (also once), using methods in Carleton 1998 and modified by Maltese & Leshner 2019.[97] 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.[98] No testing was done while the doll was on its side or in any position other than prone.[99] According to Dr. Mannen, the purpose of the test was to determine if there's an abnormal exchange of gases.[100]

Dr. Mannen testified that for a risk to exist, a product must retain or pool CO_2,[101] but she never tested how much CO_2 a Podster could retain or pool.[102]

Dr. Mannen used a mattress (with a cotton sheet) as a baseline measurement.[103] She reported that CO_2 increased from 5.6% CO_2 on the crib

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[93] CCX-1, p. 48.
[94] CCX-1, p. 48–49.
[95] CCX-1, p. 27.
[96] *Id*. *See also* Tr. 1, 131:5–13.
[97] CCX-1, pp. 27–28, 49; Tr. 1, 131:14−16; 135:4−7.
[98] CCX-1, p. 28; Tr. 1, 134:16–22.
[99] Tr. 1, 135:1–3.
[100] Tr. 1, 132:3–5.
[101] Tr. 1, 133:17–19.
[102] Tr. 1, 134:1–5.
[103] CCX-1, p. 27–28, 49; Tr. 1, 134:6−15.

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."[104] 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."[105]

For her expert report here, CCX-1, Dr. Mannen did not perform any tests on live infants.[106] And Mannen's 2019, 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.[107]

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."[108] But it's "not a perfect model," which is "why it was important to compare" the Podster test results to the "crib mattress condition."[109] But this comparison did not identify any threshold at which point rebreathing becomes problematic. The papers she relied recognize significant limitations.

Carleton 1998 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*."[110] The Carleton 1998 paper

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[104] CCX-1, p. 49.
[105] CCX-1, pp. 49–50 (citing Expert Testimony of Kr. Katwa).
[106] Tr. 1, 111:19–21.
[107] Tr. 1, 111:9–12, 18.
[108] Tr. 1, 135:15–20.
[109] Tr. 1, 135:20–22.
[110] RX-28, p. 004 (emphasis added). *See* Tr. 1, 136:4–22.

also states that "it would *not* be appropriate to *speculate* on the role that rebreathing might have played in any specific case, based solely upon these results."[111]

Further, according to Maltese & Lesher 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 facial anthropometry been examined; both of these factors may influence the interaction between the face and the sample."[112] Maltese & Leshner 2019 also caution, "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."[113]

Dr. Mannen did not conduct additional research to determine whether results based the Carleton 1998 / Maltese & Leshner 2019 methods she used could be interpreted as that which would be expected in a human infant.[114] 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."[115]

Dr. Mannen thus relied solely on the comparison between the test results of the Podster and the test result of the crib mattress.[116] But she does not know how much rebreathing is "too much" to be dangerous.[117]

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[111] RX-28, p. 005 (emphasis added). *See* Tr. 1, 137:1–12.
[112] RX-32, pp. 006–007 (emphasis added).
[113] RX-32, p. 007 (emphasis added). *See also* Tr. 1, 137:13–138:16.
[114] Tr. 1, 138:17–21.
[115] Tr. 1, 138:21–22.
[116] Tr. 1, 139:2–3.
[117] Tr. 1, 139:5–19.

Head Rotation

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.[118]

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.[119]

To conduct these measurements, Dr. Mannen placed newborn- and infant-sized CAMI dolls, supine, in intended and slouched positions.[120] 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.[121] She did each position three times in each of the ten Podsters.[122] *See id*, p. 30 (Figure 11):

[118] CCX-1, pp. 25–26, 28–29.
[119] CCX-1, pp. 29–30.
[120] CCX-1, pp. 29–30.
[121] CCX-1, pp. 29–30; Tr. 1, 122:2–11.
[122] CCX-1, pp. 29–30.

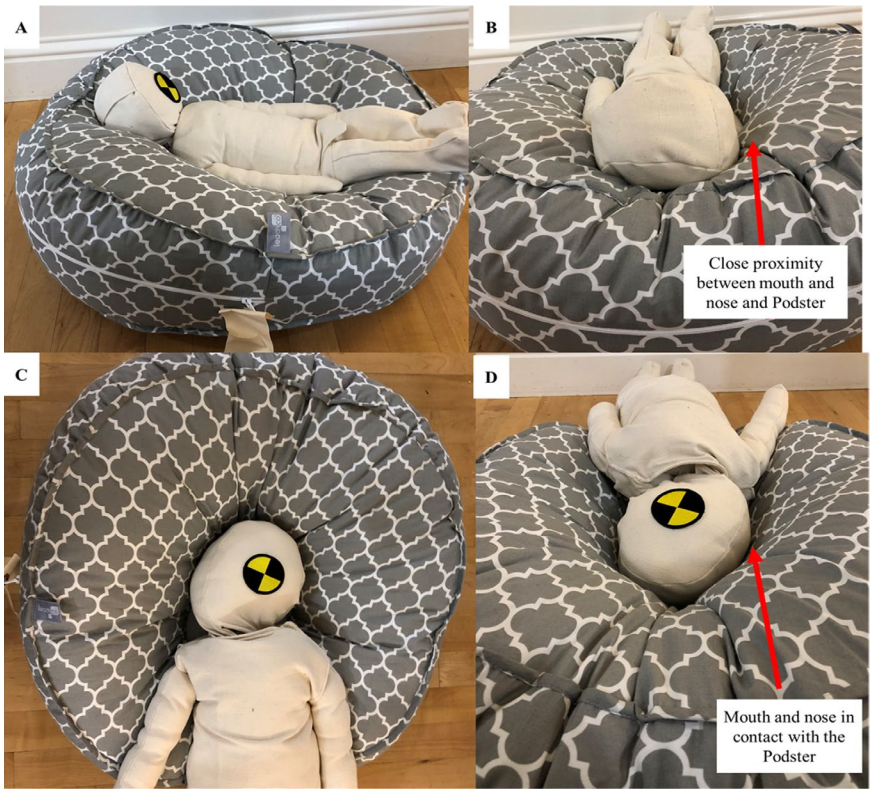

Figure 11. Photos of the head rotation testing with the newborn-sized CAMI dummy during supine lying with a 90° head turn in the (A) and (B) intended position and (C) and (D) slouched scenario on standard product.

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.[123] Instead, she created a pass/fail test: although 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.[124]

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

[123] Tr. 1, 123:9–124:2.
[124] Tr. 1, 122:13–22. *See* Tr. 3, 41:1–4 (Dr. Katwa's testifying that if the nose and mouth are not obstructed, then the risk of rebreathing is *non-existent*).

no contact between the CAMI doll's nose/mouth region and the Podster.[125] *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.

Dr. Mannen opined that a 90° head rotation of an infant in a *slouched* position results in nose/mouth contact with the Podster.[126]

Dr. Mannen's report includes a "schematic drawing"[127], purporting to compare 90° head rotations between a firm flat mattress and the Podster:

[125] CCX-1, p. 52; Tr. 1, 125:6–20; 163:19–20.
[126] CCX-1, p. 53.
[127] CCX-1, p. 54 (Figure 17)

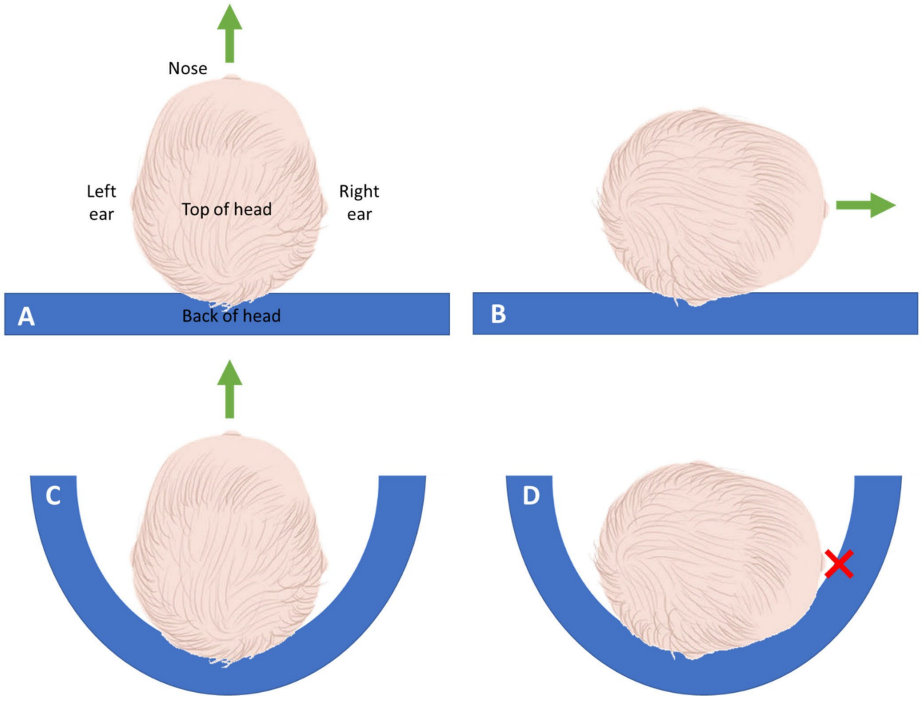

Figure 17. Schematic drawing from the top of the head looking down, where the green arrows or red x represent the nose and mouth region, depicting an infant lying supine (A) on a crib mattress with no head rotation, (B) on a crib mattress with a 90° head rotation, (C) on a soft and conforming product, 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.

This "schematic" is 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.

Dr. Mannen also took head-rotation measurements of the CAMI dolls in the prone position.[128] 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.[129] 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

[128] CCX-1, pp. 30–31.
[129] CCX-1, p. 31.

taken on a firm flat surface that "serve[d] as a control."[130] *See id.* (Figure 12):

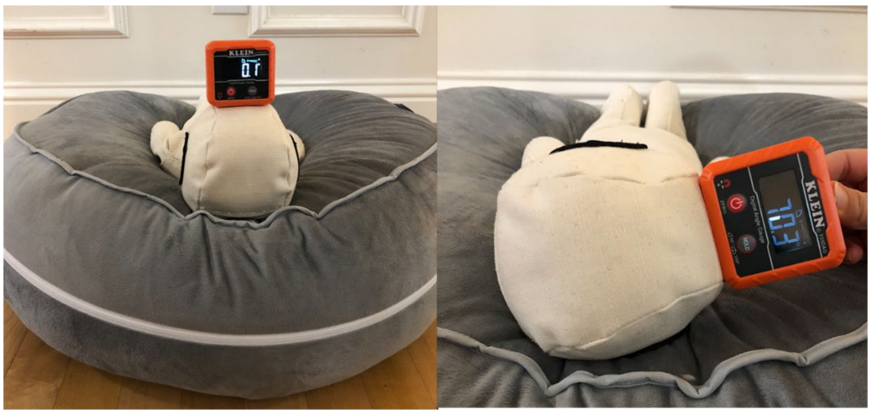

Figure 12. Photos from testing of the head rotation required during prone lying to free the mouth/nose region of the CAMI dummy to allow for free airflow.

Here, Dr. Mannen compared the head rotation purportedly "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.[131]

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.[132] 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.[133]

Dr. Mannen claimed 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.[134] But Dr. Mannen admitted

[130] CCX-1, p. 31.
[131] CCX-1, pp. 55–56.
[132] CCX-1, p. 55.
[133] CCX-1, p. 55.
[134] Tr. 1, 128:3–6.

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.[135]

The Mannen 2023 study used this head-rotation test.[136] There, 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."[137] She doesn't know.

b. The flawed methodologies in Dr. Mannen's report render the entire report unreliable.

To repeat, Dr. Mannen's testimony suffers from two primary flaws: (1) she fails to identify (with one exception that ultimately supports Leachco) any benchmarks or thresholds against which to determine if a defect or risk exists, and, even if she had identified any thresholds, (2) none of the methods employed have been peer-reviewed or validated, rendering any "conclusions" hopelessly unreliable.

Lack of Thresholds. Dr. Mannen's failure to identify thresholds and to rely solely on comparisons is alone sufficient to strike her testimony in its entirety—as courts routinely hold. 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 [product's] performance

[135] Tr. 1, 128:15–129:10.
[136] RX-36, pp. 060–066.
[137] RX-36, p. 065.

in the tests relative to ... mattresses' performance." *Id.*; *see also Smith v. Cangieter*, 462 F.3d 920, 924 (8th Cir. 2006) (holding, in automobile products-liability action that qualified mechanical engineering expert witness displayed too great an "analytical gap" between (1) fact that a part-time four-wheel drive system *could* under *some conditions* experience *some* slippage, and (2) his opinion that the system was therefore unsafe at highway speeds and required a more adequate warning, since the expert *did not know at what speeds the loss occurred*).

Here, Dr. Mannen's testimony about airflow, rebreathing, and firmness[138] is similarly "limited to showing the [Podster's] performance in the tests *relative* to ... mattresses' performance." *Rovid*, 2018 WL 5906075, at *7. And, likewise, Dr. Mannen's testimony about neck flexion, trunk flexion, rolling, and muscle fatigue[139] is limited to looking at results found in the Podster *compared to* results from testing on a mattress. *See id.*[140]

The lone exception concerns neck flexion. Here, Dr. Mannen states that the medical literature shows that a neck-flexion angle of 45° is dangerous. Tr. 1, 120:10–11. But she also conceded that she is not aware of any device that can accurately measure neck flexion. *Id.* 110:12–15; 119:2–3. So, for the only danger threshold she identified in her entire report, she admitted that she can't

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[138] *See above*, pp. 23–29.

[139] *See above*, pp. 10–23.

[140] Dr. Mannen also repeatedly qualifies her speculative "conclusions." *See, e.g.*, CCX-1, p. 11 ("[T]he Podster *could* place infants at risk of injury or death due to positional asphyxia, occlusion, or rebreathing."); *id.* p. 18 n.10 ("The steep incline of the Podster makes it *possible* for an infant to slide into a slouched position."); *id.* p. 27 ("it is *possible* that, even if air can flow through a product, carbon dioxide (CO2) will pool within a product."); *id.* p. 29 (discussing how "an infant's face *might* interact with the product"); *id.* p. 44 (lack of firmness or extra padding *could* contribute to risk); *id.* (discussing rolling on an inclined sleep product—not the Podster—and stating that "the limited horizontal space and pliant concave surface *likely* makes rolling prone to supine difficult or impossible.") (emphasis added).

accurately measure for it.[141] Further, the 45° threshold is found in Reiterer 1994.[142] 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."[143] Dr. Mannen's neck-flexion measurements were obtained by using a different (non-validated) method: CAMI dolls.[144] And the Commission's medical expert, Dr. Katwa, did not identify a proper way to measure neck flexion.[145]

Rovid is instructive, once again, with respect to Dr. Mannen's use of terms like "hazardous" or "increased risk" or "negatively affects." In *Rovid*, Leshner testified, "I define more CO2 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 CO2 rebreathing is hazardous." *Id*. Here, Dr. Mannen failed to even offer definitions for these kinds of terms.

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:

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[141] Complaint Counsel tried to support Dr. Mannen's speculations with testimony from its medical expert Dr. Katwa. But Dr. Katwa admitted that his testimony was limited to the general physiology of infant breathing in all products and circumstances. *See* Tr. 3, 8:8–9:3; CCX-3, pp. 5–16. Because Dr. Mannen's testimony fails to identify objective thresholds and because her methodologies are hopelessly flawed, Complaint Counsel has failed to demonstrate any defect that creates a risk to infants. Therefore, as explained further below, Dr. Katwa's general testimony about infant breathing is irrelevant to the facts of this case. *See Daubert*, 509 U.S. at 591–92 (holding that expert opinion testimony is not relevant unless the knowledge underlying it has a "valid ... connection to the pertinent inquiry").

[142] *See* CCX-1 (Mannen Report), p. 66 (citing Reiterer 1994); Tr. 1, 152:18–22.

[143] RX-34, p. 002.

[144] CCX-1, pp. 19–20.

[145] Tr. 3, 13:20–22.

1. Among the play yard mattresses tested, the [company's] mattresses produced the highest and most hazardous concentration of CO_2 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.

As the court in *Rovid* explained, the problems with Leshner's testimony were 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." *Id.*, 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.[146] Notably, the court here cited Carleton 1998, another paper on which Dr. Mannen relied. As

[146] At least three courts have rejected Leshner's technique as lacking a reliable methodology and validation. *See Rovid*, 2018 WL 5906075, at *7; *McKerrow v. Buyers Prods. Co.*, No. CCB-14-2865, 2016 WL 1110303, at *3 (D. Md. Mar. 22, 2016) (excluding Leshner's opinions); *Brodsky v. KaVo Dental Techs., LLC*, No. PX 15-3587, 2018 WL 620453, at *3 (D. Md. Jan. 30, 2018) (excluding Leshner's opinion because it "lacks any reliable methodology ... [and is] inadmissible without underlying validation").

Dr. Mannen admitted at the hearing,[147] and as the court in *Rovid* points out, Carleton 1998 stated that these test results could not be expected to equate results in live infants because the testing likely produces "exaggerate[d]" results compared to what a live infant would experience. *Id*.

Dr. Mannen's testimony suffers from these same defects. 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.[148] When in the "slouched" position 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.[149]

Dr. Mannen's testimony teems with these comparison "conclusions" that lack an objective threshold:

- Trunk Flexion: based on comparing the angles of the four-segment device against a baseline of 0° of a firm, flat mattress.[150]

- Head/Neck Flexion: Dr. Mannen "calculated the increase in head flexion ... compared to the normalized firm flat surface measurements."[151]

- 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, flat mattress.[152]

- Muscle Fatigue: based on the increase in muscle activity infants

[147] Tr. 1, 136:4–22.
[148] CCX-1, p. 35 (Table 1).
[149] CCX-1, p. 35 (Table 1).
[150] *See above*, pp. 10–12.
[151] *See above*, pp. 12–15.
[152] *See above*, pp. 17–21.

require on a Podster, compared to that required on a firm, flat mattress.[153]

- Rebreathing: based on comparisons between the Podster and a firm, flat mattress.[154]

- I "found significantly increased trunk flexion angle, especially compared to the firm flat crib mattress."[155]

- In the 2021 Wang study, "We compared between the firm flat crib mattress" and inclined-sleep products.[156]

- Measurement of neck angle compared to the "not realistic" rigid trunk of a CAMI doll.[157]

- For the rebreathing analysis, "I was relying on the comparison of the crib mattress…."[158]

- 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."[159]

- 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.[160]

- With respect to rebreathing, Dr. Mannen's report warns of "breathing in too much CO_2."[161] But Dr. Mannen admitted that, based on the values from the test she ran, she doesn't know how much CO_2 is "too much."[162] Instead, Dr. Mannen "used a comparison" and "talk[ed] about the data in comparison to that

[153] *See above*, pp. 21–23.
[154] *See above*, pp. 27–29.
[155] Tr. 1, 61:19–22.
[156] Tr. 1, 86:11–12.
[157] Tr. 1, 114:22–118:1.
[158] Tr. 1, 139:2–3.
[159] CCX-1, p. 24 (emphasis added).
[160] CCX-1, pp. 25–26, 28–29 (emphasis added).
[161] CCX-1, pp. 27, 49–50; *see also* Tr. 1, 131:5–13.
[162] Tr. 1, 139:15.

crib mattress condition."[163]

- 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."[164] 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."[165] But 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."[166]

- 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."[167]

- 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.[168]

- Dr. Mannen's relied 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.[169]

- 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.[170]

- 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 ....";[171] this comparison "means that

[163] Tr. 1, 139:17–19.
[164] CCX-1, p. 25.
[165] CCX-1, p. 25.
[166] CCX-1, Ex. C (Mannen 2022), pp. 215, 221.
[167] CCX-1, p. 38 (emphasis added).
[168] Tr. 1, 119:12–22 (emphasis added).
[169] CCX-1, p. 39.
[170] CCX-1, pp. 42–43; *see* Tr. 1, 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).
[171] CCX-1, p. 44 (emphasis added) (citing Mannen 2019).

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."[172]

- "'[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.'"[173]

- "'[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.'"[174]

- 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."[175]

- "[I]f an infant was breathing into" a Podster, the infant would require "*significantly more* work to breathe."[176]

- "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."[177]

- 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.[178]

- Dr. Mannen acknowledged that while there are "head-neck

[172] CCX-1, p. 44 (emphasis added) (citing Mannen 2019).
[173] CCX-1, p. 44 (emphasis added) (quoting Wang 2021).
[174] CCX-1, p. 45 (emphasis added) (quoting Wang 2021).
[175] CCX-1, p. 46 (emphasis added).
[176] CCX-1, pp. 48–49 (emphasis added).
[177] CCX-1, pp. 49–50 (emphasis added) (citing Expert Testimony of Dr. Katwa).
[178] CCX-1, p. 6.

flexion values that introduce significant breathing respiration hazards[,]" no "hard and fast" safety/danger threshold has been defined.[179]

- Dr. Mannen admitted under oath that further research is required to improve the accuracy of head-neck flexion results and to determine thresholds for safety.[180]

- Dr. Mannen is unaware of a device that can determine a threshold for safety with respect to neck flexion.[181]

- Dr. Mannen opined that the Podster "*[i]ncreases* abdominal fatigue if an infant finds themselves [sic] prone in the pillow, *increasing* the risk of suffocation."[182]

- 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."[183]

- Dr. Mannen opined that the Podster "*[n]egatively affects* the ability of an infant to breathe *normally* if they are [sic] prone or side-facing in the product.[184]

- 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.[185]

- "[O]ther researchers have reported that changes in trunk posture *can negatively impact* pulmonary and respiratory function."[186]

Lack of peer-reviewed and validated methodologies. Even if Dr. Mannen had identified thresholds, she still failed to show that any threshold "could ... be used to extrapolate [her] results to live infants." *Rovid*, 2018 WL

[179] Tr. 1, 83:13–21.
[180] Tr. 1, 109:5–110:7.
[181] Tr. 1, 110:12–15.
[182] CCX-1, p. 6 (emphasis added).
[183] CCX-1, p. 6 (emphasis added).
[184] CCX-1, p. 6 (emphasis added).
[185] CCX-1, p. 21.
[186] CCX-1, p. 39 (emphasis added).

5906075, at *8. This is so because **not one** of the methods she used for her expert testimony has been peer-reviewed or validated. Dr. Mannen heavily relied on, and followed the methodologies from, three non-peer-reviewed studies that she carried out for the CPSC—Mannen 2019, Mannen 2022, and Mannen 2023.[187] And none the other methods she employed here have been peer-reviewed or validated. For example:

- Dr. Mannen did not validate that the neck-flexion measurements she took correspond to how real infants would sit or move in a Podster.[188]

- Dr. Mannen claimed 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.[189] 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.[190]

- The Mannen 2023 study used this head-rotation test.[191] 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."[192]

Mannen does claim that two papers she relied on (and of which she is a co-author) were peer-reviewed: Wang 2020 and Wang 2021.[193] But problems remain. First, Wang 2021 used motion capture and electromyography tools to measure infants in three inclined sleeper products—tools that Dr. Mannen did

[187] Tr. 1, 83:22–85:4.
[188] Tr. 1, 82:22–83:8.
[189] Tr. 1, 128:3–6.
[190] Tr. 1, 128:15–129:10.
[191] RX-36, pp. 060–066.
[192] RX-36, p. 065.
[193] Tr. 1, 85:5–15.

not use here.[194] Further, both Wang 2020 and Wang 2021, like many of Dr. Madden's tests here, simply "compared between the firm flat crib mattress" and other products without identifying any thresholds.[195] Finally, Wang 2021 could not compare the results even among the three different products because they had not created a statistical design to do so.[196] 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.[197]

Lastly, a few examples demonstrate the complete lack of rigor applied by Dr. Mannen. As noted above, to measure trunk flexion Dr. Mannen used a four-plane sagittal device, that has not been validated.[198] But in Mannen 2023, her team used a new, *five*-segment sagittal device.[199] 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*."[200] Dr. Mannen's supposedly improved five-segment device itself still needs to be improved before it can be an accepted scientific tool.

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

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[194] *See* RX-35, p. 004; Tr. 1, 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).
[195] Tr. 1, 86:11–12; *see also* RX-34, p. 001.
[196] Tr. 1, 86:1–12; *see id.*, 97:8–98:6.
[197] Tr. 1, 86:9–12.
[198] *See above*, pp. 10–12.
[199] *See* Tr. 1, 107:8–20; RX-36 (Mannen 2023).
[200] RX-36, p. 200 (emphasis added).

placements controlled for various factors, *e.g.*, the pressure she used to push a CAMI doll into place.[201] While Leachco 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.").

Similarly problematic are Dr. Mannen's opinions that rely on contingencies 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."[202] The problem is that Dr. Mannen herself was offered to testify about the alleged dangers created by the Podster's design—not to assume them.[203]

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 [sic] prone in the pillow, increasing the risk of suffocation;"[204] that the Podster's design "[n]egatively affects the ability of an infant to breathe normally *if* they are [sic]

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[201] *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).
[202] CCX-1, pp. 49–50 (citing Expert Testimony of Dr. Katwa).
[203] *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).
[204] CCX-1, p. 5 (emphasis added).

prone or side-facing in the product;"[205] 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;"'[206] 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."[207]

One final 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.'"[208] 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.[209] 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.[210]

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.

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These methodological flaws and lack of peer review render Dr. Mannen's

[205] CCX-1, p. 5 (emphasis added).
[206] CCX-1, p. 44 (emphasis added) (quoting Wang 2021).
[207] CCX-1, p. 46 (emphasis added).
[208] CCX-1, pp. 44–45 (quoting Wang 2021) (emphasis added).
[209] Tr. 1, 140:3–8.
[210] *See above*, pp. 17–21.

testimony totally unreliable. Indeed, whether an expert's work has been "accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, *i.e.*, that it meets at least the minimal criteria of good science." *Daubert II*, 43 F.3d at 1318; *see also Williams v. Invenergy, LLC*, No. 2:13-CV-01391-AC, 2016 WL 1725990, at *11 (D. Or. Apr. 28, 2016) (distinguishing between (1) "editorial" peer review, in which as "the average [peer-reviewing] referee spends less than two hours assessing an article submitted" and (2) "true peer review," which is "is the process by which an author's peers review the author's methods and attempt to replicate the results through retesting") (citations omitted); *Valentine v. Pioneer Chlor Alkali Co.*, 921 F. Supp. 666, 674–76 (D. Nev. 1996) (same). None of Dr. Mannen's methods and results here have met the "minimal criteria of good science."

Thus, Dr. Mannen 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. The Presiding Officer should have stricken her report and testimony in its entirety.

2. Dr. Mannen's testimony should be precluded because her reliance on the Commission's IDIs is improper.

The Commission's IDIs provide only anecdotal information—they are not reliable scientific evidence. *See, e.g.*, *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 380–81 (5th Cir. 2010) (finding testimony based on "anecdotal evidence" did not meet threshold for admission of expert testimony under *Daubert* standard); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) ("anecdotal reports" about adverse events are "one of the least reliable sources to justify opinions about both general and individual causation"); *Casey*

v. Ohio Medical Prods., 877 F.Supp. 1380, 1385 (N.D. Cal. 1995) (same); *see also In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *15 (E.D. Pa. Feb. 1, 2001) (incident reports, which contain anecdotal information based on exposure to a product and alleged injury, are "universally recognized as insufficient and unreliable evidence of causation"). This is an independent basis for which the Presiding Officer should have excluded Dr. Mannen's testimony in its entirety.

3. Dr. Mannen's proffered testimony should have been excluded for failure to provide all facts known to her.

According to the Commission's Rules of Practice for Adjudicative Proceedings, parties are entitled to discover the "facts known" and opinions held by testifying experts. 16 C.F.R. § 1025.31(d). *See also* Fed. R. Civ. P. 26 (a)(2)(B)(ii) (requiring disclosure of the "facts or data considered by the witness in forming" her opinions). Dr. Mannen failed to disclose all facts she knew and relied on. As a result, her opinions—which are based on those missing facts—should have been excluded.

Dr. Mannen supported her proffered testimony with, inter alia, two Commission-sponsored studies that she completed in 2019 (concerning inclined sleepers) and 2022 (infant loungers). *See* CCX-1 (Mannen Report) at 8–11. She states that she applied the same methodology and "concepts" from those studies in her proffered report here. *See id*. at 11–13, 16.

In those 2019 and 2022 Commission-sponsored studies, Dr. Mannen reviewed and relied on 136 In-Depth Investigation reports supplied by the Commission (91 IDIs in the 2019 study and 45 IDIs in the 2022 study). *See* CCX-1 (Mannen Report), Ex. B (Mannen 2019) at 4; *id*., Ex. C (Mannen 2022) at 13. In her report here, Mannen identified the 45 IDIs from the 2022 study and stated, "I understand that CPSC has produced or will produce all of these IDIs

to Leachco." CCX-1 at 62–63. But only a few of these 45 IDIs were produced before the close of fact discovery. The vast majority were not produced until April 28, 2022—a month after the close of fact discovery (March 30, 2022). And the 91 IDIs from the 2019 study were *never* provided.

As a result, Dr. Mannen's report should have been excluded. When "a party fails to provide information" required by Rule 26, "the party is not allowed to use that information ... to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Additionally, Federal Rule of Evidence 702 requires the Court to act as a gatekeeper and preclude expert testimony that—because of an expert's failure to meet the disclosure requirements of Fed. R. Civ. P. 26—is unreliable. *See Laux v. Mentor Worldwide, LLC*, 295 F.Supp.3d 1094, 1103 (C.D. Cal. 2017).

Here, as just noted, Complaint Counsel's failure to provide all data on which Mannen relied to form her opinions cannot be justified at all. Fed. R. Civ. P. 37(c)(1). Not only did the 136 IDIs directly inform Dr. Mannen's proffered testimony here, those IDIs were responsive to Leachco's discovery requests. But Complaint Counsel refused to produce (all but a few of) these IDIs (and similar documents and information) because, it said, those documents and information were not relevant. For example, Complaint Counsel refused to produce documents "pertaining to products other than the Podsters, whether Infant Lounger Products or Infant Sleep Products" because, it said, these documents "are not reasonably calculated to lead to the discovery of admissible evidence pertaining to the issue involved in these proceedings—namely, whether Respondent's Podsters are defective and create a substantial product hazard

under Section 15 of the CPSA and applicable regulations."[211] Complaint Counsel responded similarly to Leachco's Interrogatories.[212]

Dr. Mannen's report relies on data related to those other products that the Commission previously said were not even reasonably calculated to lead to the discovery of admissible evidence. This is improper. The Commission cannot use other infant products as both a shield to withhold discovery (claiming other products are irrelevant) and a sword to prove its case (using them as evidence against the Podster).

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Therefore, the Presiding Officer erred by allowing Complaint Counsel to produce and rely on relevant and responsive documents after the fact-discovery deadline. Further, Dr. Mannen's testimony should be excluded for the failure to disclose the information required by 16 C.F.R. § 1025.31(d) and Fed. R. Civ. P. 26. *See Laux*, 295 F. Supp. 3d at 1102–03.

C. Kish's testimony should have been stricken in its entirety.

The Commission proffered the testimony of Celestine Kish to provide expert testimony on "human factors."[213] 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.

The Presiding Officer acknowledged that Kish's "surveys of public communications were not quantified," and that "she could have no way of

[211] CPSC's Resp. to Leachco's 1st RFPs No. 28.
[212] *See* CPSC's Resp. to Leachco's 1st ROGs No. 21; *see id*. Nos. 23, 25, 27, 28, 29, 30, 31, 33, 34, 38 (same).
[213] *See* CCX-2 (Kish Report). The Presiding Officer correctly ordered that all claims and evidence concerning Leachco's allegedly defective warnings were stricken. *See* Aug. 2, 2023 Order (Dkt. 128), pp. 3–5.

knowing how many consumers were influenced, and in what way, by any of the posted materials." Initial Decision 58. He nonetheless admitted her testimony into evidence (except, as noted above, for her testimony concerning the Podster's warnings, which the Presiding Officer correctly refused to admit).

But 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 made the astonishing claim that she didn't need scientific data to support her internet-search opinions.[214] Like Dr. Mannen, Ms. Kish identifies no standards or thresholds, here to determine whether and when social-media influence "pacifiers" become "too" influential or dangerous.

Consumer Influence/Pacifiers

Ms. Kish opined that "'people will often use the behavior of others to infer the appropriate action for a given situation.'"[215] Ms. Kish did not provide information to say how often this occurs.[216]

Similarly, Ms. Kish opined 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."[217] Again, Ms. Kish did not say how much "more likely" this phenomenon is.[218] Nor did Ms. Kish discuss other factors that could persuade people *not* to speed, jaywalk, etc.[219]

Ms. Kish opined that no warnings could make the Podster safe because of

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[214] Tr. 2, 92:6–8.
[215] CCX-2, p. 34 (¶66) (citation omitted).
[216] Tr. 2, 42:11–43:1.
[217] CCX-1, p. 35 (¶67) (citation omitted).
[218] Tr. 2, 43:2–5.
[219] Tr. 2, 43:6–14.

"pacifiers."[220] 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 a consumer, including observing the way other consumers interact with a product or its warnings."[221] According to Ms. Kish, "[c]ounter-examples can act as pacifiers to decrease compliance in many situations."[222] Ms. Kish testified that people are more prepared to exhibit specific patterns of behavior that they have observed.[223]

Ms. Kish stated that the internet and social media are "rife" with counter-examples.[224] But she did not define "rife."[225]

For her expert testimony, Ms. Kish ran her own searches on the internet. For example, Ms. Kish searched Instagram for posts tagged "#leachopodster".[226] This search produced 24 results, 18 of which contained images of infants sleeping in a Podster.[227] Ms. Kish opined that these images show a "significant, alarming pattern" of counter-examples that, she said, "pacify[] dangerous consumer use of the Podster."[228] But Ms. Kish did not define "pattern," nor does she say what a "significant, alarming pattern" is.[229]

Similarly, Ms. Kish later opined that certain counter-examples are "prevalent throughout the internet."[230] But Ms. Kish did not define "prevalent" and didn't attempt to quantify the supposed prevalence of these examples.[231]

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[220] *See* CCX-2, p. 34; Tr. 2, 37:2–4.
[221] CCX-2, p. 34 (¶65).
[222] CCX-2, p. 34 (¶66).
[223] Tr. 2, 40:7–13; 42:4–7.
[224] CCX-2, p. 42 (¶83).
[225] Tr. 2, 43:20–44:7.
[226] CCX-2, p. 42 (¶84).
[227] CCX-2, p. 42 (¶84).
[228] CCX-2, p. 44 (¶86).
[229] Tr. 2, 46:10–17.
[230] CCX-2, p. 53 (¶102).
[231] Tr. 2, 55:18–56:2.

Ms. Kish claimed 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."[232] But Ms. Kish never quantified how many consumers are so influenced.[233] Ms. Kish did not know how many consumers ran the searches that she ran, and she did not know how many consumers, if any, saw the results identified in her report.[234] Nor did she know how long, if at all, any consumer viewed these results.[235] She didn't study any of these questions, and she didn't know how influential any of the images she found actually are.[236]

Ms. Kish opined 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.[237] But Ms. Kish did not quantify this presumed influence, and she admitted that a consumer also could *not* be influenced by the Instagram images.[238]

Ms. Kish identified another source of purported influence on consumer behavior—an article about the Podster in *New York Magazine*.[239] Ms. Kish said that a product review in such a publication "could" influence consumer behavior.[240] But she did not identify the extent of this presumed influence. Ms. Kish further claimed that "New York Magazine is a publication that most consumers would likely view as a credible, neutral reviewer of consumer

[232] CCX-2, p. 44 (¶86).
[233] Tr. 2, 46:18–22.
[234] Tr. 2, 44:14–45:12; 47:6–10:22.
[235] Tr. 2, 45:13–15; 47:9–11.
[236] Tr. 2, 45:7–9; 48:1–3.
[237] CCX-2, p. 45 (¶87).
[238] Tr. 2, 48:10–22.
[239] CCX-2, pp. 45–46 (¶¶89–90).
[240] CCX-2, p. 46 (¶90).

products."[241] Ms. Kish admitted, however, that she didn't know how many consumers would view *New York Magazine* as a credible, neutral reviewer of consumer products; didn't know the circulation of *New York Magazine*; does not know how many subscribers the magazine has; didn't know the demographics of its readers; didn't know if *New York Magazine* regularly reviews consumer products; and didn't know if "most consumers" are even aware of *New York Magazine*.[242]

Similarly, Ms. Kish pointed to a review on Amazon.com,[243] but she didn't know, *e.g.*, how many consumers view Amazon.com each day; nor did she know how many consumers decide to buy products based on Amazon reviews; nor did she know, for example, whether motorcycle consumers are more likely to be persuaded by reviews on Amazon.com than dining-room table consumers.[244] Ms. Kish did not look study these types of questions for her report.

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.[245] She didn't study the issue at all.[246]

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.[247] Nor did Ms. Kish look for data to determine how long, if at all, any consumers viewed the examples in her report.[248] Ms. Kish did not

[241] CCX-2, p. 46 (¶90).
[242] Tr. 2, 49:4–50:7.
[243] CCX-2, p. 56 (¶107)
[244] Tr. 2, 56:4–22.
[245] Tr. 2, 50:13–22.
[246] Tr. 2, 51:5–6.
[247] Tr. 2, 51:7–13.
[248] Tr. 2, 51:14–21.

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.[249]

Foreseeable Misuse

Ms. Kish opined 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.[250]

Ms. Kish stated that consumers are likely to do "anything" to get infants to fall and stay asleep.[251] Therefore, a caregiver who perceives that an infant sleeps better in an inclined position "may be persuaded" to let the infants sleep in a Podster.[252] 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.[253] Some caregivers, Ms. Kish wrote, "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.[254] Ms. Kish further opined 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.[255] Ms. Kish said that for consumers who want to bedshare, the Podster "may be" an attractive option.[256] But Ms. Kish did not do any research to support this statement.[257]

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[249] Tr. 2, 51:22–53:15.
[250] CCX-2, p. 4.
[251] CCX-2, p. 60 (¶118).
[252] CCX-2, p. 60 (¶118).
[253] CCX-2, p. 62 (¶121).
[254] CCX-2, p. 62 (¶122).
[255] CCX-2, p. 61 (¶119).
[256] CCX-2, p. 63 (¶124).
[257] Tr. 2, 58:11–17.

Ms. Kish also said 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."[258] Ms. Kish acknowledged, however, that she had no evidence about consumers' beliefs concerning whether the Podster's design will make bedsharing safe.[259]

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."[260] But Ms. Kish admitted that she had no evidence that consumers believe the Podster's high sides will prevent overlay.[261]

Ms. Kish relied on Drago 2021.[262] According to that study, adult beds were associated with 78% or share-sleep fatalities, and the primary "fatality pattern" was overlay and probable overlay.[263] Ms. Kish admitted that this primary fatality pattern involves infants in adult beds with *or without other products*.[264]

Ms. Kish stated that Leachco's marketing "encourages" consumers to engage in "other activities" while an infant is in a Podster.[265]

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

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[258] CCX-2, p. 63 (¶124).
[259] Tr. 2, 59:12–20.
[260] CCX-2, p. 64 (¶125).
[261] Tr. 2, 60:2–9.
[262] Drago et al., "Infant fatality patterns in shared sleep: keys to intervention strategies?," *Proceedings of the 2021 HFES 65th International Annual Meeting*, 1322–26, (2021). *See* CCX-2 at p. 60 n.114.
[263] Tr. 2, 61:9–14.
[264] *Id*. 61:15–18.
[265] CCX-2, p. 61 (¶119).

will keep the infant in the product.[266]

Ms. Kish's testimony is unreliable

Assuming Ms. Kish is qualified, her testimony is unreliable. 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.'"[267] As Ms. Kish conceded, for this to occur, people must observe others engaging in the behavior in question.[268] 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.[269]

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 bedshare with their infant, the Podster may be an attractive option to

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[266] Tr. 2, 37:5–40:4.
[267] CCX-2, pp. 34–35 (¶66) (citation omitted).
[268] Tr. 2, 40:5–42:10.
[269] Tr. 2, 51:9–13; 51:22–52:2.

them,"[270] but at the hearing, Ms. Kish admitted that she did no research to determine whether that opinion was true.[271]

Finally, Ms. Kish testified that she did not "quantify the risk" at all.[272] Instead, she "look[s] at it in terms of what is about the product itself that *could* have *potential* hazards."[273]

Ms. Kish's testimony is hopelessly unreliable

As a result, Ms. Kish's testimony should have been stricken. *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

[270] CCX-2, p. 60 (¶124).
[271] Tr. 2, 58:11–16.
[272] Tr. 2, 29:9.
[273] Tr. 2, 29:13–15 (emphasis added). Indeed, even more than Dr. Mannen's testimony, Ms. Kish's testimony abounds with qualified conjecture about possible results. *See, e.g.*, CCX-3 (Kish Report), at 57 ("consumers are *likely* to do anything to get infants to fall and stay asleep."); *id.* (caregivers "*may be* persuaded to allow the infant to sleep in the Podster."); *id.* ("For parents suffering from sleep deprivation, their decision-making process *may be* impaired."); *id.* at 58 ("it is ... foreseeable that caregivers *may* intentionally sleep while the infant is asleep."); *id.* (a consumer "*may feel* comfortable allowing an infant to sleep in the Podster."); *id.* at 59 ("caregivers who are traveling or dealing with significant financial hardship with an infant *may be* more likely to allow an infant to sleep in the Podster, as they *may not* have a crib or infant sleep product readily available."); *id.* (using "may" seven additional times on page to speculate); *id.* at 60 (Podster "*may be* an attractive option" for bedsharing); *id.* at 61 (a "semi-conscious caregiver may perceive the Podster to be a pillow or form of bedding and may inadvertently roll onto it."); *id.* (caregivers may underestimate the likelihood that overlay will occur."); *id.* ("the design of the Podster ... *may* give consumers a false perception that an infant is secure."); *id.* at 62 ("A consumer *may* purchase the Podster with the intention of using it on elevated surfaces ... or *may not* understand why the product should not be used in that manner."); *id.* ("an infant *may roll* out of the Podster."); *id.* ("The Podster's *design may give* consumer a false sense of security.") (emphasis added). Not a single statement here is supported by a citation.

"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'").

Impossible and Imaginary Standard—
"Perfect Parental Supervision"

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). 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."[274] But she was forced to acknowledge that CPSC itself—like American Academy of Pediatrics and the National Institutes for Health, entities that Ms. Kish agreed are reliable organizations which provide reliable information—doesn't require perfect supervision.[275]

Indeed, both Ms. Kish and Dr. Katwa acknowledged that newborns and young infants can and do fall asleep often and in various places.[276] The CPSC itself, the American Academy of Pediatrics, and the National Institutes for Health recognize this fact, too.[277] Ms. Kish, Dr. Katwa, the CPSC, the AAP, and

[274] CCX-2, p. 5.
[275] Tr. 2, 79:14–83:18.
[276] *See* Tr. 2, 91:21 (Kish); Tr. 3, 14:6–15 (Katwa).
[277] *See* RX-2, p. 004; RX-3, pp. 003, 006; RX-37, p. 010.

the NIH all further recognize that infants can fall asleep in *unsafe*-sleep environments.[278]

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.[279] Therefore, Ms. Kish acknowledged that CPSC itself, the AAP, and the NIH don't require perfect supervision.[280]

D. Because Katwa's testimony was contingent on the testimony of Mannen and Kish—that is, because Katwa's testimony could be relevant only if other expert testimony was properly admitted—Katwa's testimony should have been stricken as irrelevant.

Leachco has no objection to the Presiding Officer's conclusion that Dr. Katwa is qualified to testify about pediatric pulmonology. And Leachco agrees that Dr. Katwa was not qualified to testify about the Podster's design, alleged use of the Podster, and alleged defective marketing by Leachco.[281] Leachco submits, however, that because the testimony of Dr. Mannen and Ms. Kish was completely unreliable, Dr. Katwa's expert medical testimony—which the Presiding Office did not strike—should have been stricken as not relevant.

Expert opinion testimony is relevant if the knowledge underlying it has a "valid ... connection to the pertinent inquiry." *Daubert*, 509 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

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[278] Tr. 2, 83:8–11; Tr. 3, 14:6–15.
[279] *See* RX-2, p. 004; RX-3, pp. 003, 006; RX-37, p. 010.
[280] Tr. 2, 83:15–18.
[281] Aug. 2, 2023 Order, Dkt. 128, pp. 6–7.

purposes." *Id.*

Applying that standard here, Dr. Katwa's testimony on the potential dangers has no bearing *in these circumstances*. Dr. Katwa's background summary regarding infant physiology, breathing, and sleep[282] 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,[283] he acknowledged that the information applies generally to all infants in all kids of circumstances.[284] And Dr. Katwa conceded that his opinions about what can happen to infants depends on infants' position and movement in the Podster.[285]

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:

> 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.

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[282] CCX-3, pp. 5–16.
[283] CCX-3, pp. 5–16.
[284] Tr. 3, 8:8–9:3.
[285] Tr. 3, 8:4–7.

Rovid, 2018 WL 5906075, at *16.

Because the opinions of Dr. Mannen and Ms. Kish are unreliable, unpersuasive, and/or unhelpful to this case, Dr. Katwa's general background information related to infant breathing—because that general information is unhelpful to the trier of fact in these circumstances—should have been stricken in its entirety.

II. THE PRESIDING OFFICER ERRED BY ADMITTING HEARSAY.

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

The Presiding Officer correctly refused to admit certain hearsay documents offered by Complaint Counsel. *See* Leachco Answering Br. But he erred in admitting other hearsay documents in its In-Depth Investigation Reports under the public-records exception to the hearsay rule.

The public-records exception allows the introduction of a hearsay statement if "it sets out" the "factual findings from a legally authorized investigation." Fed. R. Evid. 803(8)(A)(iii). This hearsay exception does not allow the admission of every statement just because it appears in a public record. Only things like investigative observations, laboratory test results, or statistical analysis are admissible under this exception. *C.O. v. Coleman Co.*, No. 06–cv–1779, 2008 WL 820066, at *2 n.6 (W.D. Wash. Mar. 25, 2008). It does not allow government investigators to "rely upon, and merely reproduce, second- or third-hand knowledge of previous events." *Id.*

Indeed, third-party statements—even if included in a public record—are themselves hearsay. *See United States v. Moore*, 27 F.3d 969, 975 (4th Cir. 1994). Accordingly, "statements by third parties who are not government employees (or otherwise under a legal duty to report) may not be admitted pursuant to the

public records exception," *United States v. Morales*, 720 F.3d 1194, 1202 (9th Cir. 2013), unless they fall within another hearsay exception, *United States v. Mackey*, 117 F.3d 24, 29 (1st Cir. 1997).

Complaint Counsel has not identified any hearsay exception that would allow the third-party statements contained within the IDIs to be admissible. Accordingly, the following documents should have been excluded:

Alabama IDI: CPSC Form 182 (at 1), CPSC Investigator's Narrative Summary (at 2–3), Exhibit 1 (at 4), Exhibit 6 (at 34–43), Exhibit 7 (at 46–52) (police report), Exhibit 7 (at 63) (CPR Training Certifications), Exhibit 7 (at 74) (sign in / out sheet), Exhibit 7 (at 75) (Face-to-Name Transition Sheet), Exhibit 7 (at 77) (statement of Farrah Wedgeworth), Exhibit 7 (at 78–79) (statement of unnamed daycare employee), Exhibit 7 (at 80) (statement of unnamed daycare employee), Exhibit 7 (at 81) (statement of unnamed daycare employee), Exhibit 7 (at 82) (statement of unnamed daycare employee), Exhibit 7 (at 83) (statement of Tyesha Hill).

Texas IDI: CPSC Form 182 (at 2), CPSC Investigator's Narrative Summary (at 4–7), Exhibit A (at 7), Exhibit D (at 16–25), Exhibit F (at 27–35) (police report), Exhibit F (at 38–41) (police officer's handwritten notes).

Virginia IDI: CPSC Form 182 (at 2), CPSC Investigator's Narrative Summary (at 4–7), Exhibit 1 (at 8), Exhibit 2 (at 9–16), Exhibit 6 (39–50), Exhibit 7 (at 51), Exhibit 11 (at 60). And from the **Virginia MECAPS**: Sudden Unexplained Infant Death Investigation Reporting Form (at 6–16).

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

Over Leachco's objection, the Presiding Officer allowed Complaint Counsel to introduce transcripts of deposition testimony by Leachco employees Mabry Ballard and Tonya Barrett provided during discovery in this case. *See* Tr. 2, 15:16–20:8. There was no dispute that these transcripts were hearsay. *Id.* But, according to the Presiding Officer, this out-of-court testimony could be admitted because Leachco's counsel attended the depositions and could have raised objections during the depositions; administrative proceedings are more lenient with respect to hearsay; and the expense of the witnesses' travel from Oklahoma to Maryland would have exceeded the benefits here. *Id.* 20:19–22:3. But that's not the correct standard.

Pursuant to Rule 32, at a hearing, "all or part of a deposition may be used against a party *on these conditions*:"

> (A) the party was present or represented at the taking of the deposition or had reasonable notice of it;
>
> (B) it is used to the extent it would be admissible under the Federal Rules of Evidence if the deponent were present and testifying; *and*
>
> (C) the use is allowed by Rule 32(a)(2) through (8).

Fed. R. Civ. P. 32(a)(1) (emphasis added); *see* 8A Fed. Prac. & Proc. Civ. § 2142 (3d ed.) [Wright & Miller] ("The restrictions imposed by Rule 32 make it clear that the federal rules have not changed the long-established principle that testimony by deposition is less desirable than oral testimony and should ordinarily be used as a substitute only if the witness is not available to testify in person.") (footnote omitted).

Complaint Counsel failed to show that it satisfied the uses allowed by Rule 32(a)(2) through (8).

The depositions were not offered to impeach either Ms. Ballard or Ms. Barrett, who were not present at the hearing since Complaint Counsel decided against calling them to testify. Fed. R. Civ. P. 32(a)(2). Neither Ms. Ballard nor Ms. Barrett was a party to this case or any party's officer, director, managing agent, or designee under Rule 30(b)(6) or 31(a)(4). Fed. R. Civ. P. 32(a)(3). Both Ms. Ballard and Ms. Barrett were available to testify; again, Complaint Counsel decided not to call them to testify at the hearing. Fed. R. Civ. P. 32(a)(4). Complaint Counsel never moved or provided notice that exceptional circumstances existed; once again, Complaint Counsel decided not to call Ms. Ballard and Ms. Barrett to testify at the hearing. Fed. R. Civ. P. 32(a)(5). None of the other factors are relevant here. *See* Fed. R. Civ. P. 32(a)(6) (allowing adverse party to introduce other parts of transcript if offering party introduces parts); Fed. R. Civ. P. 32(a)(7) (concerning substituted parties); and Fed. R. Civ. P. 32(a)(8) (concerning depositions taken in earlier actions).

Finally, while the civil rules allow depositions to be taken for purposes of using those depositions at trial, this requires agreement of the parties, *see* Fed. R. Civ. P. 29, and notice, *id.* 32(a)(5). Here, Complaint Counsel never asked that any depositions be used at trial and never provided notice. *See* Tr. 2, 19:8–12. This prejudiced Leachco because, had it known the depositions would be presented at trial, it could have asked questions during the deposition. As just discussed, Fed. R. Civ. P. 32(a)(6) allows an adverse party to introduce additional deposition testimony. Here, because the depositions of Ms. Ballard

and Ms. Barrett were *not* taken for use at trial, Leachco did not ask additional questions and was thus precluded from offering additional deposition testimony.

The Presiding Officer erred by admitting the deposition transcripts of Ms. Ballard and Ms. Barrett.

III. ARTICLE III AND DUE PROCESS VIOLATIONS

Leachco submits that the Commission's administrative hearing violated Leachco's right to a hearing before an independent judge in an Article III court and its right to due process of law.

The Constitution vests the "judicial Power of the United States" "in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." U.S. CONST. art. III, § 1. Executive Branch agencies exercise only executive power. *Id.* art. II, § 1; *see also United States v. Arthrex*, 141 S.Ct. 1970, 1985 (2021) ("Only an officer properly appointed to a principal office may issue a final decision binding the Executive Branch in the proceeding before us"). Therefore, no "judicial Power of the United States" was delegated to the Executive Branch or to any of its agencies.

But through this proceeding, the Commission—an agency of the Executive Branch—is unlawfully exercising judicial power against Leachco. The "judicial power" is the power to "bind parties and to authorize the deprivation of private rights." William Baude, *Adjudication Outside Article III*, 133 Harv. L. Rev. 1511, 1513–14 (2020).

Here, Complaint Counsel seeks an order and binding judgment that the Podster presents a "substantial product hazard" under the CPSA. The Commission further seeks an order compelling Leachco to recall the Podster and pay damages to third parties that incur recall-related costs. Accordingly, the

Commission seeks to deprive Leachco of private rights.

As a result, the Commission must follow common-law procedures—most fundamentally, through an Article III court. *Cf. Stern v. Marshall*, 564 U.S. 462, 482–84 (2011). And only courts of law, through the exercise of judicial power, may issue judgments and deprive private parties of private rights. *See Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 219 (1995) ("A judicial Power is one to render dispositive judgments.") (cleaned up). As noted above, the Presiding Officer allowed hearsay information to be introduced, likely because the Commission's rules do not afford litigants the same protections in administrative hearings that they would receive in court. *See, e.g.*, 16 C.F.R. § 1025.43(a) ("[T]he Federal Rules of Evidence may be relaxed by the Presiding Officer if the ends of justice will be better served by so doing."). Similarly, Leachco was precluded from deposing Complaint Counsel's proffered experts before the hearing (*see id.* § 1025.44)—another procedural protection that Leachco would have enjoyed in federal court (*see* Fed. R. Civ. P. 26(b)(4)(A)).

Finally, the Commission's proceedings violate the ancient maxim—protected by the Due Process Clause—*nemo iudex in causa sua* ("no one should be a judge in his own cause"). *See* THE FEDERALIST NO. 10 (Madison) ("No man is allowed to be a judge in his own cause, because his interest would certainly bias his judgment, and not improbably, corrupt his integrity."). Here, the Commission—which authorized the issuance of the administrative complaint against Leachco—has the authority to make the final decision whether Leachco has violated the CPSA and should, as a result, recall the Podster and incur significant financial penalties.

IV. CONSTITUTIONAL ISSUE PRESERVATION

Leachco respectfully maintains that the Commission is unconstitutionally structured and that this proceeding violates Leachco's constitutional rights to due process, an Article III tribunal, and a jury trial. These questions, however, cannot be addressed by the Commission. *See Carr v. Saul*, 141 S.Ct. 1352, 1360 (2021) ("[A]gency adjudications are generally ill suited to address structural constitutional challenges, which usually fall outside the adjudicators' areas of technical expertise."). Even so, to ensure that Leachco has preserved these issues should this matter be reviewed in federal court, Leachco incorporates the arguments set forth in its Motion for Summary Decision, Dkt. 91, pp. 54–62.

CONCLUSION

Here, Leachco submits that, notwithstanding the Presiding Officer's conclusion in his Initial Decision and for the purposes of preserving issues, the Presiding Officer erred in admitting certain evidence and that the Commission's administrative hearing violated Leachco's constitutional rights. A ruling Leachco's favor here would only confirm that Complaint Counsel failed to prove its claim that the Podster is a substantial product hazard under the CPSA. And Leachco does not challenge the Presiding Officer's ultimate conclusion:

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

Initial Decision 65.

DATED: October 17, 2024.

Respectfully submitted,

s/ Oliver J. Dunford

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CERTIFICATE OF SERVICE

I hereby certify that on October 17, 2024, the foregoing was served via email on the following:

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UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

[PROPOSED] ORDER

Having considered the arguments and evidence of record in this proceeding, the U.S. Consumer Product Safety Commission ("Commission" or "CPSC") concludes:

A. Complaint Counsel failed demonstrate by a preponderance of the evidence that the Podsters have a substantial design or other defect and, even if a defect might be found to exist in some technical sense, the Commission has also failed to demonstrate that such defect creates or has created a substantial risk of injury to the public.

B. The expert testimony of Erin M. Mannen, Ph.D., CCX-1, was unreliable and not helpful to the trier of fact.

C. The expert testimony of Celestine Kish, M.A., CCX-2, was unreliable and not helpful to the trier of fact.

D. The expert testimony of Umakanth Katwa, M.B.B.S., M.D., CCX-3, was not helpful to the trier of fact.

E. The Presiding Officer erroneously admitted hearsay into evidence, to wit:

i. **Alabama IDI**: CPSC Form 182 (at 1), CPSC Investigator's Narrative Summary (at 2–3), Exhibit 1 (at 4), Exhibit 6 (at 34–43), Exhibit 7 (at 46–52) (police report), Exhibit 7 (at 63) (CPR Training Certifications), Exhibit 7 (at 74) (sign in / out sheet), Exhibit 7 (at 75) (Face-to-Name Transition Sheet), Exhibit 7 (at 77) (statement of Farrah Wedgeworth), Exhibit 7 (at 78–79) (statement of unnamed daycare employee), Exhibit 7 (at 80) (statement of unnamed daycare employee), Exhibit 7 (at 81) (statement of unnamed daycare employee), Exhibit 7 (at 82) (statement of unnamed daycare employee), Exhibit 7 (at 83) (statement of Tyesha Hill).

ii. **Texas IDI**: CPSC Form 182 (at 2), CPSC Investigator's Narrative Summary (at 4–7), Exhibit A (at 7), Exhibit D (at 16–25), Exhibit F (at 27–35) (police report), Exhibit F (at 38–41) (police officer's handwritten notes).

iii. **Virginia IDI**: CPSC Form 182 (at 2), CPSC Investigator's Narrative Summary (at 4–7), Exhibit 1 (at 8), Exhibit 2 (at 9–16), Exhibit 6 (39–50), Exhibit 7 (at 51), Exhibit 11 (at 60). And from the **Virginia MECAPS**: Sudden Unexplained Infant Death Investigation Reporting Form (at 6–16).

iv. Transcripts from the depositions of Mabry Ballard.

v. Transcripts from the deposition of Tonya Barrett.

* * *

IT IS THEREFORE ORDERED:

1. The expert testimony of Erin M. Mannen, Ph.D., CCX-1, is hereby stricken in its entirety.

2. The expert testimony of Celestine Kish, M.A., CCX-2, is hereby stricken in its entirety.

3. The expert testimony of Umakanth Katwa, M.B.B.S., M.D., CCX-3, CCX-1, is hereby stricken in its entirety.

4. The hearsay evidence identified in Paragraph E above is hereby removed from evidence as improper hearsay.

5. The relief sought in the Complaint is **DENIED**.

6. The Complaint is **DISMISSED**.

DATED: _____

ORDER OF THE COMMISSION

_____
Alberta E. Mills
Secretary
U.S. Consumer Product Safety Commission