

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

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August 4, 2023

In the Matter of

LEACHCO, INC.,

CPSC Docket No. 22-1

Respondent.

FINAL PREHEARING ORDER

Commission Rules direct issuance of a final prehearing order after the conclusion of the final prehearing conference. 16 C.F.R. § 1025.21(e) (2023). A final prehearing conference was held in this matter, pursuant to Rule 21 of the Commission's Rules of Practice for Adjudicative Proceedings on July 11, 2023, at 11 a.m. eastern time. This Order reviews the remaining requirements and provides information necessary for controlling the course of the hearing.

Counsel appeared as follows:

For the Commission staff:

Brett Ruff
Michael J. Rogal
Gregory Reyes

For the Respondent:

Oliver J. Dunford
Frank Garrison

1. *Nature of Action and Jurisdiction.* This is an action for an alleged substantial product hazard, and the Commission is invoked under the United States Code, Title 15, Section 2064, and under the Code of Federal Regulations, Title 16, Sections 1025 and 1115. Through its constitutional claims, Respondent challenges the authority of the Commission to proceed against it.

2. *Stipulations and Statements.* The following stipulations and statements were submitted on July 18, 2023. They are attached to and made part of this Order:

(a) *A comprehensive written stipulation or statement of all uncontested facts.*

1. Leachco is an Oklahoma corporation founded in 1988 by Jamie Leach and Clyde Leach.
2. Leachco manufactures, distributes, and offers for sale more than 90 products for infants, children, and adults.
3. Leachco sells its products throughout the United States through retailers.
4. Leachco sells some of its products on its website www.leachco.com.
5. Jamie Leach is Leachco's Vice President and Chief of Product Development.
6. Jamie Leach designs Leachco's products.
7. Clyde Leach is Leachco's President and Chief Executive Officer.
8. Leachco has approximately 30 employees and is located in Ada, Oklahoma.
9. In this proceeding, "Podster" or "Podsters" refers to different models of Leachco infant loungers, including the Podster, Podster Plush, Bummzie, and Podster Playtime models.
10. The Podsters were manufactured in Leachco's facilities in Ada, Oklahoma.
11. The Podsters were distributed and offered for sale to consumers for their personal use.
12. The Podster was first sold in 2009.
13. Since 2009, Leachco has manufactured and distributed in U.S. commerce approximately 180,000 Podsters.
14. The retail price for the Podster ranges from \$49 to \$89.
15. Leachco's website at <https://leachco.com/collections/baby/products/podster> states in part: "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. The adjustment tabs provide versatile support, cinch them in to create a cozier and more secure seat for smaller infants or release them to create a larger area for growing infants. The Podster provides upper body elevation, which can help aid in digestion and breathing."
16. Leachco's website at <https://leachco.com/pages/important-info> states in part: "The Podster® 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."
17. The main panel of the Podster's packaging contains the following warning: "For healthy infants ages newborn and up. Not intended for use by preemies. WARNING! TO PREVENT SERIOUS INJURY OR DEATH: Constant adult supervision is required at all times. Do not allow the baby to lie face down or on side in the Podster®. For use on floor only. Never place in the crib, on the bed, table, playpen, counter or any elevated surface. Never move the Podster® while baby is on it. Do not use for sleeping. Intended to be used by healthy infants not to exceed 16 pounds, or until infant is able to roll over, push up on hands and knees; whichever is achieved first. Never leave child unattended."
18. The Podster is not and has never been advertised by Leachco as a sleep product.

19. The Podster contains warnings that the product should not be used for sleep and that adult supervision is always required.
20. The Podster contains warnings that the product should only be used on the floor, and not in another product, such as a crib, on a bed, table, playpen, counter, or any elevated surface.
21. The Podster contains warnings that infants should not be placed prone or on their side in the product.
22. The Podster contains instructions that it should be used for infants not to exceed 16 pounds and should not be used if an infant can roll over.
23. The Podster contains warnings and instructions that use of the product in contravention to these warnings could result in serious injury or death.
24. Joint Exhibits JX-3 through JX-50 are authentic in this proceeding.
25. Complaint Counsel's exhibits CCX-1 through CCX-43 are authentic in this proceeding.
26. Respondent Leachco's exhibits RX-1 through RX-27 are authentic in this proceeding.

Joint Stipulations at 1–3 (July 14, 2023).

(b) *A concise summary of the ultimate facts as claimed by each party.*

Complaint Counsel.

Leachco is an Oklahoma corporation that manufactures, distributes, and offers for sale products including pillows for infants, children, and caregivers. It markets and sells products through its own website as well as through Amazon.com, Walmart and others. Jamie Leach, Vice President and Chief of Product Development, is a former practicing nurse and designed Leachco's products. Clyde Leach is the President and Chief Executive Officer. The corporation has approximately 50 employees and is located in Ada, Oklahoma. Leachco has generated millions of dollars in revenues, including approximately \$6.5 million in 2022, and \$7 million in 2021.

The Podster is not and has never been a top selling product. The Podster is an infant lounging pillow with various models. Leachco has manufactured and distributed approximately 180,000 Podsters for retail prices ranging from \$49 to \$89. The purpose of the Podster, per Ms. Leach, is to provide "a hands-free place for an infant to lounge." Compl. Counsel's Prehr'g Br. 3 (July 14, 2023). The packaging and website market the Podster as "a Sling-Style Infant Lounger" that "provides a warm and cozy caress for infants" and "provides upper body elevation which can help aid in digestion and breathing," as well as featuring "deeply contoured sides" that hold the infant. *Id.* Marketing materials claim an adult can multitask hands-free while an infant is in the Podster, allowing a caregiver to "prepare a meal, pay bills, check email, give a hand to siblings and many other daily tasks." *Id.* at 4.

Leachco did not conduct any safety testing regarding suffocation hazard prior to selling the Podster. It did conduct testing for lead and sharp edges, but did not test incline angles,

firmness, airflow, infant positioning, or carbon dioxide rebreathing levels to determine whether a potentially fatal suffocation hazard for infants existed.

The Podster presents several design defects that create a suffocation hazard, including: airflow obstruction; lack of firmness; facilitation of movement on the Podster; facilitation of movement off the Podster; allowance of rolling; positional asphyxia, and leading to unsafe bedsharing.

The Commission presents Dr. Erin Mannen, a biomechanical engineering expert, testified to these defects, testifying:

1. The Podster's design causes a flexed head/neck and flexed trunk posture during supine lying, inhibiting normal breathing;
2. The Podster's design facilitates some types of rolling on or off of the product, introducing concerning suffocation-related risks for the infant;
3. The Podster increases abdominal fatigue if an infant finds themselves prone in the pillow, increasing the risk of suffocation;
4. The Podster negatively affects the ability of an infant to self-rescue from the prone position to a safe breathing position;
5. The Podster permits an infant in a supine position to move its face into the sides of the Podster where its nose and mouth are obstructed; and,
6. The Podster negatively affects the ability of an infant to breathe normally if they are prone or side-facing in the product.

Br. 6. These conclusions were based on examination of the following: incline angles; facilitation of rolling; muscle fatigue and ability to self-rescue; firmness; airflow; infant positioning; and carbon-dioxide rebreathing.

Caregivers will and do use the Podster for infant sleep, despite warnings and instructions that it should not be used for sleep, that an infant should always be supervised, and that caregivers should use the Podster on the floor. This is based on the following reasons: caregivers are motivated to have infants fall and stay asleep and will permit it if achieved on the Podster; many caregivers are influenced by social media or other images showing infants sleeping on the Podster;¹ some traveling caregivers lack a readily available, safe infant sleep product; as a pillow marketed for infant use, it does not appear hazardous; caregivers may use for bedsharing or co-sleeping, relying on the design, even if they have some appreciation of the risks; and caregiver use for sleep is confirmed by three reported incidents of infant deaths associated with use of the Podster.

Caregivers will leave infants unsupervised because the activities listed in the Podster's marketing necessarily take attention away from supervising an infant. Consumers are unlikely to appreciate the risk of rolling or movement into a compromised position because the Podster

¹ The Commission presents Ms. Celestine Kish, an engineering psychologist, who provides examples of the Podster being used for sleep by parents or caregivers.

creates a false sense of security. Supervision lapses are inevitable and alternatives for unsupervised safe sleep exist.

It is foreseeable consumers will use the Podster for bedsharing, on elevated surfaces, or within other products, creating a suffocation hazard because: adults can roll onto infants during sleep; infants can suffocate on soft bedding; and infants can become entrapped between the mattress and adjoining surface. Even caregivers educated on risks may find the Podster an attractive option if they wish to bedshare and may wrongly perceive the Podster's sides as a barrier. Caregivers may also wrongly perceive the contoured sides will negate a fall risk if used on an elevated surface. It is similarly foreseeable caregivers will place infants in the Podster contained in other products.

Infants in a Podster may suffer severe injury or death. Even in the intended supine position, the design may cause neck flexion, impacting an infant's airway. Infants may move into a slouched position in the inclined, soft, and compressible design, risking positional asphyxia.² Infants who roll or move into a position where their face is pressed into the Podster's soft pillow surface can suffer brain hypoxia—lower levels of oxygen and higher levels of carbon dioxide. Infants can therefore suffer suffocation or death within minutes in any of the evaluated positions.

There have been three reported incidents of infant deaths, involving suffocation, associated with use of the Podster. Infants are a uniquely vulnerable population, and each incident involved foreseeable use of the Podster for sleep within a sleep space—in a crib, between parents on an adult bed, and inside a playpen.

Respondent.

Leachco, a small, family-owned and run business, has designed and manufactured childcare products, including those designed for infant care, for 35 years. Jamie Leach designs Leachco products and has secured over 40 patents and dozens of trademarks. Ms. Leach's husband and all their children, a son-in-law, and granddaughter have worked at the company.

The Podster was developed and patented in 2008. It is a lounger that lets a caregiver place an infant in a reclined position during supervised, awake time. The design features a sling seat with adjustment tabs for custom fit. It was designed to help with daytime care of awake infants to free up caregivers' hands. Leachco has sold over 180,000 Podsters.

The Commission asserts the Podster is a “substantial product hazard” under the CPSA. It acknowledges:

[T]hat the Podster is not and has never been advertised as a sleep product; that the Podster contains warnings that the product should not be used for sleep and that

² The Commission presents Dr. Umakanth Katwa, a pediatric pulmonologist, who provides that such positioning creates abdominal pressure, negatively affecting the diaphragm and creating muscle fatigue.

adult supervision is always required; that the Podster contains warnings that the product should only be used on the floor, and not in another product, such as a crib, on a bed, table, playpen, counter, or any elevated surface; that the Podster contains warnings that infants should not be placed prone or on their side in the product; that the Podster contains instructions that it should be used for infants not to exceed 16 pounds, and should not be used if an infant can roll over; and that the Podster contains warnings and instructions that use of the product in contravention to these warnings could result in serious injury or death.

Leachco, Inc.’s Prehr’g Br. 6 (July 14, 2023).

The Commission alleges that the Podster is defectively designed because it is foreseeable—despite the warnings and instructions—that consumers will misuse it by allowing infants to sleep in it, will not supervise infants in it, and will use it for bedsharing. The Commission requests an order that Leachco issue a notice to the public of the hazard, conduct a recall, refund purchasers, and pay damages to third parties who incur recall-related costs.

(c) Written stipulations or statements setting forth the qualifications of the expert witnesses to be called by each party.

Complainant.

Expert Test. of Erin Mannen, Ph.D., at 6–8, Ex. A (Apr. 28, 2023)

Expert Test. of Celestine T. Kish, M.A., at 2–6, Ex. 1 (Apr. 28, 2023)

Expert Test. of Umakanth Katwa, M.B.B.S., M.D., at 5, Ex. A (Apr. 28, 2023)

Respondent.

Peggy Shibata, Investigative Report, Esi Matter No. 95469, at 3–4, Appx. A (Apr. 28, 2023)

(d) Written lists of the witnesses whom each party will call, written lists of the additional witnesses whom each party may call, and a statement of the subject matter on which each witness will testify.

Complaint Counsel provided a list of five witnesses it planned to present at hearing: Konica McMullen, Erin Mannen, Celestine Kish, Umakanth Katwa, and Jamie Leach. Compl. Counsel’s Witness List, at 1–3 (July 14, 2023). It further provided a list of possible witnesses it may present: Christopher Nguyen, John Walker, Christopher Palmer, and Elizabeth Phillips. *Id.* at 3–4. Ms. McMullen has been excluded as a witness. *See* Order Reaff’g Decision to Grant Leachco, Inc.’s Mot. to Strike Konica McMullen from the Comm’n’s Witness List, at 3 (Aug. 2, 2023) (“McMullen Strike”).

Respondent provided a list of five witnesses it plans to present at hearing: Jamie Leach, Peggy Shibata, Umakanth Katwa, Celestine Kish, and Erin Mannen. Witness List of Resp't Leachco, Inc., at 1 (July 14, 2023). It further provided a list of possible witnesses it may present: Alex Leach, Clyde Leach, Mabry Ballard, Tonya Barrett, Leah Barnes, Zachary Foster, Hope Nesteruk, Suad Wanna-Nakamura, and [again] Celestine Kish. *Id.* at 2. Complaint Counsel has not challenged any of the listed witnesses.

(e) An agreed statement of the contested issues of fact and of law, or separate statements by each party of any contested issues of fact and law not agreed to.

Complainant.

Do the Podsters contain “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,” thus presenting a “substantial product hazard” under 15 U.S.C. § 2064(a)(2)?

Respondent.

1. Can the Commission prove by a preponderance of the evidence that the Podster has a “product defect”?
2. If the Commission can prove that the Podster has a “product defect,” can the Commission prove by a preponderance of the evidence that the alleged defect creates a risk of injury to the public?
3. If the Commission can prove that the Podster has a product defect and that the defect creates a risk of injury to the public, can the Commission prove by a preponderance of the evidence that the risk is “substantial”?

(f) A list of all depositions to be read into evidence and statements of any objections thereto.

Complaint Counsel may request during the hearing that portions of the depositions of Jamie Leach, Clyde Leach, and Alexander Leach (see CCX-4 to CCX-6) be accepted into evidence under 16 C.F.R. § 1025.35(i)(2).

Respondent will not read any depositions into evidence and will assert hearsay objections if Complaint Counsel moves to admit depositions into evidence. Respondent also reserves, in addition to its hearsay objection, the objection that the witnesses were not designated as corporate designees for their depositions.

(g) A list and brief description of any charts, graphs, models, schematic diagrams, and similar objects that will be used in opening statements or closing arguments but will not be offered in evidence. If any other such objects are to be used by any party, those objects will be submitted to opposing counsel at least three days prior to the hearing. If there is then any objection to their use, the dispute will be submitted to the Presiding Officer at least one day prior to the hearing.

Neither party will have any charts or other objects for opening / closing that will not be offered into evidence.

(h) Written waivers of claims or defenses which have been abandoned by the parties.

Neither party intends to submit written waivers of claims or defenses that have been abandoned by the parties.

3. Complaint Counsel's Evidence.

Complaint Counsel offered 57 exhibits. Exhibits CCX-1 through 56 were provided in its prehearing exhibit list. *See* Compl. Counsel's Ex. List, at 1–3 (July 14, 2023). Exhibit CCX-57 was offered and marked in a later, permitted Offer of Proof. *See* McMullen Strike at 3. Exhibit CCX-58 was also marked in a subsequent Offer of Proof. *See* Order Marking Compl. Counsel's Offer of Proof Regarding the Decl. of Konica McMullen as Ex. CCX-58 at 1 (Aug. 4, 2023).

Complaint Counsel only requested admission of Exhibits CCX-6–12B into evidence. This Court deferred ruling on that motion. *See* Order Deferring Decision on Compl. Counsel's Mot. in Lim. & Mem. in Supp. to Admit In-Depth Investigation Reps., at 4 (Aug. 2, 2023).

No exhibits have been admitted. The authenticity of Exhibits CCX-1 through 43 have been stipulated. Compl. Counsel's Ex. List, at 1; Joint Stipulations ¶ 25.

4. Respondent's Evidence.

Respondent offered 27 exhibits. Exhibits RX 1 through 27 were provided in its prehearing exhibit list. *See* Leachco, Inc.'s Ex. List, at 1–3 (July 14, 2023).

No exhibits have been admitted. The authenticity of Exhibits RX-1 through 27 have been stipulated. Joint Stipulations ¶ 26.

5. Joint Exhibits.

The parties offered 50 joint exhibits. Exhibits JX-1 through 50 were provided in a prehearing exhibit list. *See* Joint Exhibit List, at 1–4 (July 14, 2023).

No exhibits have been admitted. The authenticity of Exhibits JX-3 through 50 have been stipulated. Joint Stipulations ¶ 24.

6. *Limitations and Reservations.*

Additional Witnesses. Additional witnesses beyond those listed will only be allowed upon application to the Presiding Officer.

Rebuttal Witnesses. Rebuttal witnesses not listed in the exhibits to this order may be called only if the necessity of their testimony could not reasonably be foreseen 10 days prior to trial. If it appears to counsel at any time before trial that such rebuttal witnesses will be called, notice will immediately be given to opposing counsel and the Presiding Officer.

Hearing. The probable length of hearing is 10 days. The hearing will commence on Monday, August 7, 2023, at 9 a.m. eastern time. It will be held in the Commission's hearing room: 4330 East West Hwy, Room 420, Bethesda, MD 20814.

Prehearing Briefs. Prehearing briefs were submitted on July 14, 2023. All anticipated legal questions for hearing were stated, and motions related to the admissibility of evidence were submitted concurrently or thereafter. This Court has rule on all evidentiary challenges or deferred until hearing.

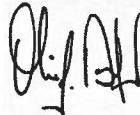
This Prehearing Order has been formulated after a conference at which counsel for the respective parties appeared. Reasonable opportunity has been afforded counsel for corrections or additions prior to signing. It will control the course of the hearing, and it may not be amended except by consent of the parties and the Presiding Officer, or by order of the Presiding Officer to prevent manifest injustice.



Michael G. Young
Administrative Law Judge



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