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In the Matter of)	
)	
)	
LEACHCO, INC.)	CPSC DOCKET NO. 22-1
)	
)	Hon. Michael G. Young
)	Presiding Officer
Respondent.)	
)	

Pursuant to 16 C.F.R. § 1025.22 and the Court’s September 16, 2022 Order on Prehearing Schedule, Complaint Counsel hereby submits this Prehearing Brief containing: (1) a statement of the facts expected to be proved and the anticipated order of proof; (2) a statement of the issues and the legal arguments in support of Complaint Counsel’s contentions with respect to those issues; and, (3) a table of authorities relied upon.

Complaint Counsel will prove by a preponderance of the evidence that the Podster pillows manufactured and distributed by Respondent Leachco, Inc. (“Leachco”) present a substantial product hazard pursuant to Section 15 of the Consumer Product Safety Act (“CPSA”). The evidence will show that the Leachco Podster pillows (“Subject Products”) present a substantial product hazard because they have “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). The condition creating the risk—the inclined, compliant, soft, and insufficiently permeable design of

the Podsters—constitutes the basic character of the Podsters, and this amounts to a design defect. This also is a design defect because a risk of severe injury—including risk of death—to the uniquely vulnerable infant populations “occurs as a result of the operation or use of the product.” 16 C.F.R. § 1115.4.

II. STATEMENT OF FACTS AND ORDER OF PROOF

A. Respondent Leachco, Inc.

Leachco is an [REDACTED].¹

Leachco manufactures, distributes, and offers for sale more than 90 products, including pillows for infants, children, and nursing caregivers. Leachco markets and sells its products [REDACTED]

[REDACTED]

[REDACTED].²

Jamie Leach is [REDACTED].³ She is also

[REDACTED].⁴ Ms. Leach [REDACTED].⁵

Clyde Leach is [REDACTED].⁶ Leachco has [REDACTED]

[REDACTED].⁷

Leachco has generated [REDACTED] from the sale of its various products. In 2022, Leachco’s revenues [REDACTED].⁸ In 2021,

¹ Jamie Leach Deposition, March 1, 2023 at 15:2-4 (Exhibit 1 to Declaration of Michael J. Rogal in Support of Complaint Counsel’s Motion for Partial Summary Decision, Dkt. No. 90) (hereinafter “Rogal Decl.”).

² Complaint, Dkt. No. 1, ¶ 12; Answer, Dkt. No. 2, ¶ 11; Alex Leach Deposition, February 15, 2023 at 82:3-16 (Rogal Decl. Exhibit 2).

³ Jamie Leach Deposition, March 1, 2023 at 16:1-4, 17:18-20 (Rogal Decl., Exhibit 1); Leachco Organizational Chart, May 11, 2022, Leachco-CPSC-000002 (Rogal Decl., Exhibit 3).

⁴ Jamie Leach Deposition, March 1, 2023 at 12:6-13, 22:17-23:15 (Rogal Decl., Exhibit 1).

⁵ *Id.* at 28:4-20 (Rogal Decl. Exhibit 1).

⁶ Clyde Leach Deposition, February 28, 2023 at 33:4-8 (Exhibit 4); Leachco Organizational Chart, May 11, 2022, Leachco-CPSC-000002 (Rogal Decl., Exhibit 3).

⁷ Leachco’s Responses to CPSC’s First Set of Interrogatories, May 13, 2022, at 2 (response to Interrogatory No. 3) (Rogal Decl., Exhibit 5); Clyde Leach Deposition, February 28, 2023 at 62:14-17 (Rogal Decl., Exhibit 4).

⁸ Clyde Leach Deposition, February 28, 2023 at 88:21-89:8 (Rogal Decl., Exhibit 4).

Leachco's revenues [REDACTED].⁹ [REDACTED]

[REDACTED].¹⁰ The Podster infant lounging pillow [REDACTED]

[REDACTED].¹¹

B. The Subject Products—The Leachco Podster

The Subject Products are various models of the “Podster” infant lounging pillows, including the Podster, Podster Plush, Bummzie, and Podster Playtime models.¹² The Podsters are manufactured in Leachco's facilities in Ada, Oklahoma.¹³ The Podsters are distributed and offered for sale to consumers for their personal use.¹⁴ Since 2009, Leachco has manufactured and distributed approximately 180,000 Podsters.¹⁵

Leachco sold the Podster for a retail price ranging from \$49 and \$89.¹⁶ According to Jamie Leach, [REDACTED]

[REDACTED] Leachco's marketing materials claim that an adult can multitask

⁹ *Id.* at 88:21-89:4 (Rogal Decl., Exhibit 4).

¹⁰ Web Data Collection, February 7, 2023 for www.leachco.com/collections/leachco-catalog (Rogal Decl., Exhibit 6); Alex Leach Deposition, February 15, 2023 at 83:18-21 (Rogal Decl., Exhibit 2); Clyde Leach Deposition, February 28, 2023 at 99:10-104:7 (Rogal Decl., Exhibit 4).

¹¹ Alex Leach Deposition, February 15, 2023 at 83:8-13 (Rogal Decl., Exhibit 2); Clyde Leach Deposition, February 28, 2023 at 104:7-105:7 (Rogal Decl., Exhibit 4).

¹² Complaint, Dkt. No. 1, ¶ 7, 9; Answer, Dkt. No. 2, ¶ 7, 9.

¹³ Complaint, Dkt. No. 1, ¶ 8; Answer, Dkt. No. 2, ¶ 8.

¹⁴ Complaint, Dkt. No. 1, ¶ 7; Answer, Dkt. No. 2, ¶ 7.

¹⁵ Complaint, Dkt. No. 1, ¶ 10; Answer, Dkt. No. 2, ¶ 10.

¹⁶ Complaint, Dkt. No. 1, ¶ 11; Answer Dkt. No. 2, ¶ 10.

¹⁷ Jamie Leach Deposition, March 1, 2023 at 86:16-22 (Rogal Decl., Exhibit 1).

¹⁸ See Exhibit A; Jamie Leach Deposition, March 1, 2023 at 157:1-158:10 & Ex. 9 (Leachco Podster webpage); Leachco's Objections and Responses to CPSC's Second Set of Requests for Admission, November 30, 2022, Response to RFA No. 2 at 1-2 (Rogal Decl., Exhibit 7).

hands-free while an infant is in the Podster—meaning a caregiver may engage in activities like “prepare a meal, pay bills, check email, give a hand to siblings and many other daily tasks.”¹⁹

Prior to selling the Podster, [REDACTED]

[REDACTED]²⁰ Leachco [REDACTED]

[REDACTED]²¹

C. *The Podster’s Design Defects*

The Podster presents several design defects that create a suffocation hazard. The Podster is defective because:

- **Airflow obstruction.** It can cause airflow obstruction if an unsupervised infant rolls, moves, or is placed in a position where the infant’s nose and mouth are obstructed by the Podster.²²
- **Lack of Firmness.** It is constructed of thick, soft padding that has a concave shape which can envelop an infant’s face and cause airflow obstruction if an unsupervised infant rolls, moves, or is placed in a position where the infant’s nose and mouth are obstructed by the Podster;²³

¹⁹ Expert Testimony of Celestine Kish, May 2, 2023 at 63 (Rogal Decl., Exhibit 10) (quoting Leachco’s website).

²⁰ Jamie Leach Deposition, March 1, 2023 at 87:14-20 (Rogal Decl., Exhibit 1); Tonya Barrett Deposition, February 1, 2023 at 77:11-21 (Rogal Decl., Exhibit 8).

²¹ Exhibit A: Jamie Leach Deposition, March 1, 2023 at 34:14-35:8; Tonya Barrett Deposition, February 1, 2023 at 36:15-37:14, 76:21-77:13 (Rogal Decl., Exhibit 8); Clyde Leach Deposition, February 28, 2023 at 116:2-121:6 (Rogal Decl., Exhibit 4); Clyde Leach Deposition Exhibit No. 3 (Podster Test Reports, LC-88-167) (Rogal Decl., Exhibit 9).

²² Expert Testimony of Erin Mannen, Ph.D., April 28, 2023 at 6, 41, 58 (Declaration of Brett Ruff in Support of Complaint Counsel’s Response in Opposition to Leachco, Inc.’s Motion for Summary Decision, June 23, 2023 (Dkt. 96) (hereinafter “Ruff Decl.”) Exhibit 9).

²³ *Id.* at 21, 46-47.

- **Facilitates Movement on the Podster.** It facilitates an infant's movement on the Podster, enhancing the risk that the infant's nose and mouth will be obstructed by the Podster;²⁴
- **Facilitates Movement off of the Podster.** It facilitates an infant's movement off the Podster, enhancing the risk that the infant's nose and mouth will be obstructed by another object in the infant's environment, such as soft bedding;²⁵
- **Allows Rolling.** It allows an infant to roll, even if the infant is not able to roll on a flat surface, such as in a crib or bassinet;²⁶
- **Positional Asphyxia.** Its shape and design cause increased flexion that inhibits breathing and enable an infant to slide down into the seat of the product, causing further increased flexion that further inhibits breathing;²⁷ and,
- **Leads to Unsafe Bedsharing.** Its design also can lead to unsafe bedsharing where the infant sleeps in an adult bed with one or more adult caregivers.²⁸

Dr. Erin Mannen, Complaint Counsel's biomechanical engineering expert, testified that the Podster contains numerous design defects outlined above, which pose suffocation hazards for infants. Dr. Mannen's expert opinions can be summarized as follows:

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;

²⁴ *Id.* at 41-43.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at 18 n.10, 36-40.

²⁸ Expert Testimony of Celestine Kish, May 2, 2023 at 60-61 (Rogal Decl., Exhibit 10)

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.²⁹

Dr. Mannen's expert testimony presented specific conclusions regarding incline angles, firmness, airflow, infant positioning, and carbon dioxide rebreathing levels:

- **Incline angles.** Dr. Mannen's testimony explains that the inclined nature of the Podster presents certain hazards related to how the infant sits and how that affects the infant's breathing.³⁰ Dr. Mannen's finding was that the head and thigh angles of the Podster are similar to dangerous inclined sleep products.³¹ Dr. Mannen's testing found that the head angles averaged approximately 30 and 24 degrees, respectively, for newborn- and infant-sized gage devices and the thigh angle averaged approximately 57 degrees for both devices, each of which falls within the range that was determined to be dangerous for infants.³²
- **Facilitation of Rolling.** Dr. Mannen concluded that the Podster's design facilitates rolling within or off the product, which can lead to the mouth and nose of the infant becoming obstructed.³³ Dr. Mannen compared the Podster's mechanical environment to a firm flat surface and determined that the Podster's

²⁹ Expert Testimony of Erin Mannen, Ph.D., April 28, 2023 at 5-6 (Ruff Decl., Ex. 9).

³⁰ *Id.* at 32-34.

³¹ *Id.* at 32.

³² *Id.* at 32-34.

³³ *Id.* at 42.

design permits infants to achieve a roll more easily and with less coordinated movements.³⁴

- **Muscle Fatigue and Ability to Self-Rescue.** Dr. Mannen’s expert opinion is that the design of the Podster causes abdominal muscle fatigue and thus negatively affects an infant’s ability to self-rescue from a position in which the infant’s nose and mouth are obstructed.³⁵
- **Firmness.** Dr. Mannen’s expert testimony details her measurements of the firmness of the Podster, how much the product conforms under the weight of an infant, and how that contributes to body position and suffocation risk by making breathing more difficult.³⁶ Dr. Mannen’s main conclusion was that “the Leachco Podster pillows exhibited an average of 1.75” greater displacement (nearly 3.5 *times greater*) compared to crib mattresses.”³⁷
- **Airflow.** Dr. Mannen’s expert testimony contains data and analysis of airflow testing of the Podster that demonstrate the negative effects on an infant’s breathing when interacting with the product.³⁸ Dr. Mannen’s main finding was that Podsters “exhibited *over 10 times less airflow* . . . compared to the recommended threshold.”³⁹
- **Infant Positioning.** Dr. Mannen’s expert testimony is that if infants rotate their heads 90 degrees during supine-lying it “results in mouth and nose contact with the soft sides of the Leachco Podster if an infant is placed in the slouched position

³⁴ *Id.*

³⁵ *Id.* at 44-46.

³⁶ *Id.* at 46-48.

³⁷ *Id.* at 47 (emphasis in original).

³⁸ *Id.* at 48-49.

³⁹ *Id.* at 48 (emphasis in original).

or otherwise had slid down into the recessed portion of the pillow.”⁴⁰ This positioning and head movement where the nose and mouth are in contact with the plush sides of the Podster presents a “concerning suffocation scenario because of the decreased airflow and increased CO₂ inhalation.”⁴¹

- **Carbon-Dioxide Rebreathing.** Dr. Mannen also presents her data and analysis regarding CO₂ rebreathing.⁴² The main conclusion there is that the Leachco Podster demonstrated an increase of nearly 2.5 times the amount of CO₂ rebreathing as compared to a crib mattress, which served as the control group. The result of this is, according to Dr. Mannen’s expert testimony, that “O₂ decreases and the CO₂ substantially increases, increasing the risk for hypoxia (not breathing enough oxygen) and breathing in too much CO₂.”⁴³

D. Consumer Use of the Podster For Sleep

According to Leachco’s marketing and warnings, the Podster should not be used for sleep and an infant on a Podster should always be supervised by an adult.⁴⁴ Leachco instructs that parents and caregivers should use the Podster on the floor with an awake infant and constantly supervise the infant.⁴⁵

Despite Leachco’s warnings and instructions, caregivers use the Podster for infant sleep.⁴⁶ There are several reasons why this occurs. First, parents and caregivers are motivated to have infants under their care fall and stay asleep for extended periods of time. If that sleep can be

⁴⁰ *Id.* at 52.

⁴¹ *Id.* at 53.

⁴² *Id.* at 49-51.

⁴³ *Id.* at 49-50.

⁴⁴ Complaint, Dkt. No. 1, ¶ 14-15; Answer Dkt. No. 2, ¶¶ 13-14.

⁴⁵ Expert Testimony of Celestine Kish, May 2, 2023 at 57 (Rogal Decl., Exhibit 10).

⁴⁶ Complaint, Dkt. No. 1, ¶ 23; Answer, Dkt. No. 2, ¶ 22.

achieved on the Podster, parents and caregivers may permit infants to sleep in it.⁴⁷ [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]⁴⁸ Leachco also admitted that it knew “some consumers had placed some infants on some Podsters and some infants subsequently fell asleep on the product” and that “consumers allowed infants to sleep on Podsters.”⁴⁹ [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]⁵⁰ [REDACTED]
[REDACTED]
[REDACTED]⁵¹ [REDACTED]

Second, the Podster is used for sleep because many parents and caregivers are influenced by social media and other images showing infants sleeping on the Podster. Scientific research shows that consumer compliance with warnings is influenced by other consumers’ behaviors towards the product. Current safe sleep recommendations are often ignored by parents and caregivers in the face of counter-examples that depict unsafe behaviors.⁵² These include social media posts and images showing consumers using the Podster for sleep, as well as recommendations and discussions on retailer sites such as Amazon.com and parenting websites, all of which contribute to social influencing that can lead to consumers to disregard the warnings and use the Podster for sleep.⁵³ Celestine Kish, an engineering psychologist with over three

⁴⁷ Expert Testimony of Celestine Kish, May 2, 2023 at 57 (Rogal Decl., Exhibit 10).

⁴⁸ *Id.* at 70-71 (Rogal Decl., Exhibit 10); Mabry Ballard Deposition, January 31, 2023 at 180:15–19 (Rogal Decl., Exhibit 14); Tonya Barrett Deposition, February 1, 2023 at 27:20–28:12, 29:8–30:9 (Rogal Decl., Exhibit 8).

⁴⁹ Leachco’s Second Supplemental Response to CPSC Request for Admission Nos. 3, 4, & 5, March 13, 2023 at 2 (second supplemental response to RFA No. 3) (Rogal Decl., Exhibit 11).

⁵⁰ Alex Leach Deposition, February 15, 2023 at 141:8-16 (Rogal Decl., Exhibit 2).

⁵¹ Leah Barnes Deposition, February 16, 2023 at 118:18-120:10, 132:19-134:8 (Rogal Decl., Exhibit 16) [REDACTED]
[REDACTED]
[REDACTED]

⁵² Expert Testimony of Celestine Kish, May 2, 2023 at 34-39 (Rogal Decl., Exhibit 10).

⁵³ *Id.* at 39-53 (Exhibit 10); Leachco’s Second Supplemental Response to CPSC RFA Nos. 3, 4, & 5, March 13, 2023 at 5 (second supplemental response to RFA No. 5) (Rogal Decl., Exhibit 11) (admitting that Leachco “had

decades of experience in her field, provided various real-life examples in her expert testimony where the Podster was being used for sleep by parents or caregivers.⁵⁴

Third, the Podster is used for sleep because some parents and caregivers who are traveling may be without a safe infant sleep product that is readily available.⁵⁵

Fourth, because the Podster is a pillow that is marketed for infant use and does not appear hazardous, consumers are unlikely to be alerted to the risks of using it for sleep. For instance, parents and caregivers may not appreciate that an infant can move or roll into an unsafe position.⁵⁶

Fifth, parents and caregivers may use the Podster for bedsharing or co-sleeping. Even parents and caregivers that have some appreciation of the risks of bedsharing may mistakenly believe that the Podster's raised sides and sling design will keep infants securely positioned, when in fact use of the Podster for bedsharing does not eliminate suffocation risk.⁵⁷

Finally, tragically, the three reported incidents of infant deaths associated with use of the Podster confirm that caregivers will use the Podster for sleep. In each of the three fatal incidents, the infant was placed in the Podster for sleep before suffocating.⁵⁸

The testimony of Leachco's expert, Ms. Shibata, does not materially contradict this expert testimony and the research cited by Ms. Kish.⁵⁹

E. Consumer Use of the Podster Without Constant Supervision

Leachco's warnings require "constant adult supervision" but also claim an adult can

knowledge that there were reviews on Amazon.com that referenced infants sleeping on Podsters").

⁵⁴ Expert Testimony of Celestine Kish, May 2, 2023 at 39-53 (Rogal Decl., Exhibit 10).

⁵⁵ *Id.* at 59 (Rogal Decl., Exhibit 10).

⁵⁶ *Id.* at 2 (Rogal Decl., Exhibit 10).

⁵⁷ *Id.* at 60-61 (Rogal Decl., Exhibit 10).

⁵⁸ *Id.* at 67-70 (Rogal Decl., Exhibit 10); Expert Testimony of Umakanth Katwa, April 28, 2023 at 26-29 (Rogal Decl., Exhibit 13); *see also* Leachco's Objections and Responses to CPSC First Set of Requests for Admission, November 30, 2022 at 3-4 (Response to RFA No. 6) (Rogal Decl., Exhibit 7).

⁵⁹ *See* Expert Testimony of Peggy Shibata, April 28, 2023 at 10 (Rogal Decl., Exhibit 12).

multitask hands-free while an infant is in the Podster—meaning a caregiver may engage in activities like “prepare a meal, pay bills, check email, give a hand to siblings and many other daily tasks.”⁶⁰ Yet by engaging in these other household activities, a parent or caregiver necessarily is taking attention away from supervising the infant in the Podster.⁶¹ Consumers are not likely to appreciate that infants can roll or move into a compromised position, unable to self-rescue, and suffocate within minutes.⁶² The Podster’s design provides a false sense of security to caregivers that an infant can be safely left unsupervised.⁶³ Scientific research demonstrates—and common sense supports—that multitasking necessarily takes attention away from one activity as others are performed, and caregivers simply cannot be perfectly attentive, regardless of their desire to do so.⁶⁴ Lapses in supervision when using a Podster—which are inevitable—can have fatal consequences. Alternatives for unsupervised safe sleep exist for parents, including regulated infant products such as play yards, bassinets, and cribs, which are subject to mandatory standards requiring a safe sleep surface.⁶⁵ The testimony of Leachco’s expert, Ms. Shibata, does not materially contradict this expert testimony and the research cited by Ms. Kish.⁶⁶

F. Consumer Use of the Podster for Bedsharing, on Elevated Surfaces, or Within Another Product

Despite Leachco’s warnings, it also is foreseeable that consumers will use Podsters for bedsharing, on elevated surfaces, or within other products, such as cribs and play yards.

Bedsharing, sometimes referred to as “co-sleeping,” poses a suffocation hazard because adults

⁶⁰ Expert Testimony of Celestine Kish, May 2, 2023 at 63 (Rogal Decl., Exhibit 10) (quoting Leachco’s website).

⁶¹ *Id.* at 62-63 (Rogal Decl., Exhibit 10).

⁶² *Id.* at 62 (Rogal Decl., Exhibit 10).

⁶³ *Id.*

⁶⁴ *Id.* at 63-64 (Rogal Decl., Exhibit 10). Nothing in Peggy Shibata’s expert testimony contradicts Ms. Kish’s expert testimony regarding the impossibility of constant supervision while using the Podster.

⁶⁵ *Id.* at 63 (Rogal Decl., Exhibit 10). Leachco’s expert, Peggy Shibata, does not contradict or address these safe alternatives in her testimony. Expert Testimony of Peggy Shibata, April 28, 2023 at 14 (Rogal Decl., Exhibit 12).

⁶⁶ *See id.* at 10 (Rogal Decl., Exhibit 12) (asserting that less-safe alternatives for lounging include couches or adult beds, but not disputing play yards, bassinets and cribs can be safe for sleep).

can roll onto infants during sleep (overlay), the infant can suffocate on soft bedding, or the infant can become entrapped between the mattress and an adjoining surface, such as a wall.⁶⁷ If a caregiver wishes to bedshare with their infant, the Podster may be an attractive option to them, as the Podster is soft, portable, and can easily be brought into the bed.⁶⁸ Even caregivers who have been educated on the risks of bedsharing may wrongly perceive that the Podster’s high sides will act as a barrier between the adult and the infant to protect the infant from overlay.⁶⁹ Caregivers may also wrongly believe that the Podster’s raised sides, in combination with the “sling” design, will keep infants securely positioned in the product.⁷⁰ However, there is no evidence that the Podster’s high sides will eliminate the risk of overlay,⁷¹ and Dr. Mannen provided evidence that the design of the Podster can cause an infant to roll off of it and onto an adult bed.

Placing the Podster on an elevated surface such as a couch, table, or counter creates a fall hazard if an infant rolls out of the Podster.⁷² Nevertheless, caregivers may use the Podster on elevated surfaces.⁷³ Indeed, the design of the Podster, with the “deeply contoured sides” that Leachco highlights in its marketing materials, may give consumers a false perception that an infant is secure in the Podster and lead them to place the Podster on unsafe, elevated surfaces or objects.⁷⁴

It also is foreseeable that caregivers will place infants on Podsters that are themselves contained within another product, such as a crib or play yard. The use of the Podster in a crib or similar product creates yet another safety hazard—entrapment, which can lead to suffocation.⁷⁵ If

⁶⁷ *Id.* at 60 (Rogal Decl., Exhibit 10).

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.* at 61 (Rogal Decl., Exhibit 10).

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 62 (Rogal Decl., Exhibit 10).

an infant is placed on a Podster inside a crib, an infant may roll out of the Podster and become entrapped between the Podster and the side of the crib.⁷⁶ In addition, if the Podster is used on a bed or couch, an infant could roll off the product and become entrapped in the environment (e.g., between the mattress and headboard, or between couch cushions).⁷⁷ Consumers who believe the Podster’s design and its “deeply contoured sides” will keep an infant sufficiently in place in the Podster may not appreciate this entrapment hazard.⁷⁸

G. Infants in a Podster May Suffer Severe Injury or Death

The Podster presents several scenarios that can cause severe injury or death to an infant. First, even in the intended supine position, an infant can suffer from neck flexion due to the inclined and compressible design of the Podster.⁷⁹ Neck flexion can significantly impact an infant’s airway, and biomechanical studies have found that infants lying at an inclined angle are at risk of airway collapse.⁸⁰ As a result, if the infant’s airway is blocked or collapsed, air cannot enter the lungs, which results in progressive and severe hypoxemia, cardiorespiratory arrest, and death.⁸¹

Second, the Podster’s inclined, soft, and compressible design facilitates infant movement.⁸² Infants can move into a slouched position and be at risk of positional asphyxia, even in the supine position.⁸³ Dr. Umakanth Katwa, a lecturer at Harvard Medical School and an attending physician in the Division of Pulmonary Medicine at Boston Children’s Hospital, has testified that the slouched position creates abdominal pressure, which negatively affects the

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ Expert Testimony of Umakanth Katwa, April 28, 2023 at 10 (Rogal Decl., Exhibit 13).

⁸⁰ *Id.* at 10-11 (Rogal Decl., Exhibit 13).

⁸¹ *Id.* at 11 (Rogal Decl., Exhibit 13).

⁸² *Id.* at 4 (Rogal Decl., Exhibit 13).

⁸³ *Id.* at 20 (Rogal Decl., Exhibit 13).

diaphragm, and also creates muscle fatigue. Neck flexion in the slouched position also creates a risk of airway compression like in the intended position.⁸⁴ Airway compression and obstructive breathing caused by this position can lead to prolonged hypoxemia, increased carbon dioxide inhalation, unconsciousness, and death.⁸⁵

Third, infants who roll or move into a position in which their face is pressed into the Podster's soft pillow surface can suffer from lower levels of oxygen and higher levels of carbon dioxide, which can result in brain hypoxia.⁸⁶ Because infants have developing and immature respiratory systems, it can take as little as 2 to 3 minutes for an infant to become non-responsive due to suffocation.⁸⁷ Infants who move into a hazardous position have difficulty self-rescuing because they do not have the strength to move out of the position.⁸⁸ Prone sleep presents several risks to an infant, including negatively affecting protective reflexes that would permit arousal, and increasing the risk of rebreathing elevated levels of carbon dioxide and lower levels of oxygen.⁸⁹ Infants also tend to get more REM sleep than older children and adults, and, during REM sleep, infants are more at risk of respiratory compromise.⁹⁰

Regardless of whether the infant is placed in the supine, intended position, whether the infant has moved into a slouched position, or whether an infant moves or rolls into a prone position, the medical evidence detailed by Dr. Katwa's testimony demonstrates that infants can suffer from suffocation and death within minutes.⁹¹ The risk of severe injury or death was also confirmed by Dr. Katwa's review of the fatal incidents involving infants associated with using a

⁸⁴ *Id.* at 21 (Rogal Decl., Exhibit 13).

⁸⁵ *Id.* (Rogal Decl., Exhibit 13); *see also* Deposition of Tonya Barrett, February 1, 2023 at 150:4-22 (Rogal Decl., Exhibit 8) [REDACTED]

⁸⁶ Expert Testimony of Umakanth Katwa, April 28, 2023 at 21 (Rogal Decl., Exhibit 13).

⁸⁷ *Id.* at 4 (Rogal Decl., Exhibit 13).

⁸⁸ *Id.* at 19 (Rogal Decl., Exhibit 13).

⁸⁹ *Id.* at 21 (Rogal Decl., Exhibit 13).

⁹⁰ *Id.* at 14 (Rogal Decl., Exhibit 13).

⁹¹ *Id.* at 25-26 (Rogal Decl., Exhibit 13).

Podster for sleep in Alabama, Texas, and Virginia.⁹² The testimony of Leachco's expert, Ms. Shibata, does not materially contradict this expert testimony and the research cited by Dr. Katwa.⁹³

H. Fatal Incidents

Tragically, in this case there have been three reported incidents of infant deaths associated with use of the Podster. In each of the three fatal incidents, the infant was placed in the Podster for sleep before suffocating.⁹⁴ These incidents resulted in fatalities to infants, a uniquely vulnerable population. Each of the three incidents also involved foreseeable use of the Podster for sleep. And in each instance, the Podster was placed on or within a sleep space (a crib, an adult bed, and a playpen) to allow the infant to sleep. In the Alabama incident, Dr. Katwa testified that the infant was placed to sleep in a Podster in a crib and was found face down in the Podster. Dr. Katwa concluded that the postmortem from the Alabama incident showed evidence that the cause of death was most likely due to prolonged hypoxemia.⁹⁵ In the Texas incident, Dr. Katwa testified that an infant was placed to sleep between her parents on an adult bed, and concluded that the unsafe sleep environment led to suffocation with prolonged hypoxemia resulting a brain damage and death.⁹⁶ In the Virginia incident, Dr. Katwa testified that an infant was placed to sleep in a Podster inside a playpen, and noted the cause of death was found to be unsafe bedding and positioning, and that the unsafe sleep environment increased the risk of

⁹² *Id.* at 26-29 (Exhibit 13). Nothing in Leachco's expert testimony contradicts Dr. Katwa's findings regarding the risk or serious injury and/or death due to suffocation risk. *See* Expert Testimony of Peggy Shibata, April 28, 2023 (Rogal Decl., Exhibit 12).

⁹³ *See* Expert Testimony of Peggy Shibata, April 28, 2023 at 5-7 (Rogal Decl., Exhibit 12).

⁹⁴ Expert Testimony of Celestine Kish, May 2, 2023 at 67-70 (Rogal Decl., Exhibit 10); Expert Testimony of Umakanth Katwa, April 28, 2023 at 26-29 (Rogal Decl., Exhibit 13); *see also* Leachco's Objections and Responses to CPSC First Set of Requests for Admission, November 30, 2022 at 3-4 (Response to RFA No. 6) (Rogal Decl., Exhibit 7).

⁹⁵ Expert Testimony of Umakanth Katwa, April 28, 2023 at 26-27 (Rogal Decl., Exhibit 13).

⁹⁶ *Id.* at 27 (Rogal Decl. Exhibit 13).

suffocation, even in the side position of the Podster where the infant was found.⁹⁷ Thus, Dr. Katwa found that in all three infant deaths, the incidents were associated with use of a Podster, and this contributed to risk of suffocation and death.

I. Order of Proof

Complaint Counsel's anticipated order of proof is to present the facts in approximately the order in which they are described in this prehearing brief. Complaint Counsel first expects to call a consumer witness, the parent of the infant victim in the Alabama incident, who is expected to detail in her testimony her experience with her son and her account of the incident. Complaint Counsel then expects to call its mechanical biomedical engineering expert, Dr. Mannen, to describe her experiments, data, and analysis of the Podster. Third, Complaint Counsel intends to put on its human factors engineering expert, Celestine Kish, to discuss consumer use of the Podsters and consumer interaction with the product and its warnings and instructions. Fourth, Complaint Counsel will call its medical expert, Dr. Katwa, to testify about the serious risk of injury or death posed by the Podster. Further, based on the discussions at the Final Prehearing Conference on July 11, 2023, and Leachco's representation that Jamie Leach will appear in person at the hearing, Complaint Counsel expects to call Ms. Leach in its case regarding, among other things, the design, testing, and marketing of the Podster. Finally, based on the Prehearing Conference, the parties agreed to in-person testimony and Complaint Counsel expects all of its and Leachco's witnesses to appear live and in-person at the CPSC Bethesda location.

At the moment, Leachco is disputing the admissibility of every exhibit on the parties' Joint Exhibit List, including samples of the Podster itself, reports Leachco made to the CPSC, and investigatory reports prepared by CPSC employees. Although Complaint Counsel hopes that

⁹⁷ *Id.* at 28–29 (Rogal Decl. Exhibit 13).

Leachco will agree to the admissibility of many of the joint exhibits by the time of the hearing so as to streamline the hearing and achieve its efficient resolution, if Leachco does not so stipulate, then Complaint Counsel expects to call approximately four other witnesses for the limited purpose of establishing the admissibility of certain of the joint exhibits.

III. STATEMENT OF ISSUES

Complaint Counsel intends to submit the following issue for the Presiding Officer's determination:

1. 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)?

IV. LEGAL ARGUMENTS

A. Complaint Counsel Must Prove its Case By a Preponderance of the Evidence

Complaint Counsel must prove its case by a preponderance of the evidence. The rules governing this proceeding provide that the Court's "Initial Decision shall be based upon a consideration of the entire record and shall be supported by reliable, probative, and substantial evidence." 16 C.F.R. § 1025.51(b). Section 15(f)(1) of the CPSA, 15 U.S.C. § 2064(f)(1), adopts the hearing standards of Section 554 of the Administrative Procedure Act, which, in turn, applies the provisions of Section 556 of the APA to adjudicatory proceedings. 5 U.S.C. §§ 554, 556.

The Supreme Court of the United States has held that where a statute requires "substantial evidence," "adjudicatory proceedings subject to the APA satisfy the statute where determinations are made according to the preponderance of the evidence." *Steadman v. SEC*, 450 U.S. 91, 101-02, 104 (1981). The Commission concurs with this analysis and expressly has held

that “the preponderance of the evidence standard applies” to Section 15 administrative proceedings. *See In re Zen Magnets*, 2017 WL 11672449, *6-7 (CPSC October 26, 2017), *aff’d in part and rev’d in part on other grounds*, 2018 WL 2938326 (D. Colo. June 12, 2018), *aff’d in part and rev’d in part on other grounds*, 968 F.3d 1156 (10th Cir. 2020).

The preponderance of the evidence burden of proof “simply requires the trier of fact ‘to believe that the existence of a fact is more probable than its nonexistence before he may find in favor of the party who has the burden to persuade the judge of the fact’s existence.’” *Concrete Pipe & Products of California, Inc. v. Constr. Laborers Pension Trust for S. California*, 508 U.S. 602, 622 (1993), *quoting In re Winship*, 397 U.S. 358, 371–72 (1970) (Harlan, J., concurring). Complaint Counsel will satisfy this standard.

B. The Subject Products are a Substantial Product Hazard Under Section 15(a)(2) Because they Contain Product Defects Which Create a Substantial Risk of Injury to the Public

The CPSA provides that the Commission may order a firm to stop sale of a consumer product, recall the product, and provide notice to the public about the recall if the product “presents a substantial product hazard.” CPSA § 15(c), (d), 15 U.S.C. § 2064(c), (d). Under CPSA Section 15(a)(2), a “substantial product hazard” is “a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.” 15 U.S.C. § 2064(a)(2).

A “defect” may include a defect in the product’s design or warnings. 16 C.F.R. § 1115.4. A design defect may be present “even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public.” 16 C.F.R. § 1115.4. Further, a design defect may also be present “if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended,” 16 C.F.R.

§ 1115.4, and a “risk of injury” includes “a risk of death, personal injury, or serious or frequent illness.” CPSA § 3(a)(14), 15 U.S.C. § 2052(a)(14). In determining whether a risk of injury renders a product defective, the Commission considers the following factors, 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 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.

Because the Subject Products contain a design defect which creates a substantial risk of injury to the public, the Subject Products present a substantial product hazard within the meaning of CPSA Section 15(a)(2). Accordingly, this Court should order the Respondent to stop sale of the Subject Products and implement a corrective action, including a recall and public notice of the recall.

1. The Subject Products Contain Design Defects by Virtue of the Physical Design of the Products

The physical design of the Podster is defective and presents a risk of injury to the public—specifically, uniquely vulnerable infants. As explained in further detail above, Dr. Mannen testified that several aspects of the design of the Podster render the Podster defective. Standing alone, any one of the design defects renders the Podster defective. Together, they create a great risk of death to infants placed in the product.

- **The Podsters’ Incline Angles Negatively Affect Infant Breathing and Can Lead to Sliding Down Within the Product.** Dr. Mannen testified that the inclined design of the Podster presents certain hazards related to how the infant

sits and how that affects the infant's breathing.⁹⁸ And Dr. Katwa elaborated that the flexion that results from that positioning poses a risk of asphyxiation to infants, even if they are placed in the intended position.⁹⁹ Furthermore, the inclined design of the Podster allows infants to slide into a slouched position where the flexion is even more pronounced and the risk of asphyxia is more severe.¹⁰⁰

- **The Podsters Facilitate Rolling.** Dr. Mannen concluded that the Podster's design facilitates rolling within or off the product, which can lead to the mouth and nose of the infant becoming obstructed.¹⁰¹ Dr. Mannen compared the Podster's mechanical environment to a firm, flat surface and determined that the Podster's design permits infants to achieve a roll more easily and with less coordinated movements than if they were on a firm, flat surface such as a crib mattress.¹⁰² Dr. Katwa also testified that "the Podster, due to its unsafe design, makes it easy for an infant to roll from a supine into a prone or side position, where the infant's face will get enveloped by or pressed against the soft surface of the U-shaped pillow portion of the Podster, resulting in nose and mouth occlusion and suffocation."¹⁰³
- **The Podsters Increase Muscle Fatigue and Reduce an Infant's Ability to Self-Rescue.** Dr. Mannen testified that that the physical design of the Podster, such as its inclined nature, causes abdominal muscle fatigue and thus negatively affects an

⁹⁸ Expert Testimony of Erin Mannen, April 28, 2023 at 32-34 (Ruff Decl., Exhibit 9).

⁹⁹ Expert Testimony of Umakanth Katwa, April 28, 2023 at 30 (Rogal Decl., Exhibit 13).

¹⁰⁰ Expert Testimony of Erin Mannen, April 28, 2023 at 18 n.10 (Ruff Decl., Exhibit 9); Expert Testimony of Umakanth Katwa, April 28, 2023 at 21-22, 30 (Rogal Decl., Exhibit 13).

¹⁰¹ Expert Testimony of Erin Mannen, April 28, 2023 at 42 (Ruff Decl., Exhibit 9).

¹⁰² *Id.*

¹⁰³ Expert Testimony of Umakanth Katwa, April 28, 2023 at 30 (Rogal Decl., Exhibit 13).

infant's ability to self-rescue if the infant finds itself in a position in which the infant's nose and mouth are obstructed, whether through rolling or otherwise.¹⁰⁴

Dr. Katwa also explained:

“During suffocation, due to the design of the Podster, it is very difficult for the infant to leverage its weight against the soft, highly flexible Podster and to lift its head and turn the head to clear the nose and mouth to breathe. Infants may need up to 70-degree rotation of the head to clear the nose to breathe from prone position, and developmentally young infants have not yet achieved muscle strength to do such maneuvers. Therefore, this makes it almost impossible for the infant to self-rescue from the prone or side position in the Podster.”¹⁰⁵

- **The Podsters' Lack of Firmness Creates a Risk of Suffocation.** Dr. Mannen testified that the Podsters are substantially softer than a crib mattress.¹⁰⁶ As Dr. Katwa testified: “This increases the risk for suffocation and rebreathing when infants roll over to the prone or side sleeping position.”¹⁰⁷ Indeed, “[t]he Podster's surface is very soft and highly compressible, and, without an underlying rigid back surface, the infant will be unable to leverage their weight against this highly compressible surface to lift the neck and rotate their head to self-rescue and clear their nose if the infant is in a prone or side sleeping position.”¹⁰⁸
- **The Podsters Place Infants in Positions Where Their Breathing Can Be Compromised.** Dr. Mannen's expert testimony is that, due to the physical design of the Podster, if infants rotate their heads 90 degrees during supine-lying it “results in mouth and nose contact with the soft sides of the Leachco Podster if an infant is placed in the slouched position or otherwise had slid down into the

¹⁰⁴ Expert Testimony of Erin Mannen, April 28, 2023 at 44-46 (Ruff Decl., Exhibit 9).

¹⁰⁵ Expert Testimony of Umakanth Katwa, April 28, 2023 at 30 (Rogal Decl., Exhibit 13).

¹⁰⁶ Expert Testimony of Erin Mannen, April 28, 2023 at 47 (Ruff Decl., Exhibit 9).

¹⁰⁷ Expert Testimony of Umakanth Katwa, April 28, 2023 at 19 (Rogal Decl., Exhibit 13).

¹⁰⁸ *Id.*

recessed portion of the pillow.”¹⁰⁹ This positioning and head movement where the nose and mouth are in contact with the plush sides of the Podster presents a “concerning suffocation scenario because of the decreased airflow and increased CO₂ inhalation.”¹¹⁰

- **The Podsters’ Design Allows for Insufficient Airflow and Promotes Carbon-Dioxide Rebreathing.** Dr. Mannen testified that, by virtue of their design, Podsters “exhibited *over 10 times less airflow* . . . compared to the recommended threshold.”¹¹¹ Dr. Mannen also presented data and analysis regarding CO₂ rebreathing.¹¹² The main conclusion there is that the design of the Podster causes an increase of nearly 2.5 times the amount of CO₂ rebreathing as compared to a crib mattress, which served as the control group. The result of this is, according to Dr. Mannen’s expert testimony, that “O₂ decreases and the CO₂ substantially increases, increasing the risk for hypoxia (not breathing enough oxygen) and breathing in too much CO₂.”¹¹³ Dr. Katwa, in turn, evaluated this restricted airflow and elevated CO₂ data and explained:

“Airflow data from Dr. Mannen’s biomechanical testing revealed that there is close to a 10-fold pressure drop when testing in the prone position, resulting in substantially reduced air flow. This results in a drop in volume of air with each breath (termed as tidal volume), meaning the infant must breathe faster to breathe in the same amount of air it typically could breathe in one minute if airways are unobstructed (minute ventilation). Dr. Mannen’s analysis of airflow in the prone position revealed that there is reduced airflow which also increases the CO₂ by 9.4% (a three-fold increase) and drops oxygen by 1.8%. If the reduced airflow continues to occur for greater than 10 minutes, it can result in profound hypoxemia and unconsciousness resulting in irreversible brain damage and/or brain death.

¹⁰⁹ Expert Testimony of Erin Mannen, April 28, 2023 at 52 (Ruff Decl., Exhibit 9)

¹¹⁰ *Id.* at 53.

¹¹¹ *Id.* at 48 (emphasis in original).

¹¹² *Id.* at 49-51.

¹¹³ *Id.* at 49-50.

Even if the infant is resuscitated at this time, complete neurological recovery is very unlikely to happen, leading to irreversible neurological damage such as cerebral palsy and vegetative state requiring breathing and feeding support for life. If the hypoxemia lasts longer than 25 minutes, it can result in death and the infant may not even be able to be resuscitated.”¹¹⁴

Taken alone, each of these aspects of the design of the Podsters renders the product defective. Together, they create a particularly dangerous product than can prove fatal to its infant occupants.

2. The Subject Products Contain Design Defects Because a Risk of Injury Occurs as a Result of Their Operation and Use

A design defect may be present if a risk of injury occurs as a result of the operation or use of the product. Section 1115.4 explicitly says that “a design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended.” The regulations also explicitly says consideration of whether a product is defective shall include, among other things, “the role of consumer misuse of the product and the foreseeability of such misuse.” 16 C.F.R. § 1115.4(e). *See also Zen Magnets v. CPSC*, No. 17-cv-02645-RBJ, 2018 WL 2938326, *7 (D. Colo. June 12, 2018), *aff’d in part and rev’d in part on other grounds*, 968 F.3d 1156, 1176 (10th Cir. 2020) (finding that under 1115.4 “[a]lthough adequate instructions and safety warnings might prevent misuse . . . misuse can be a basis for finding a product defective”); *In the Matter of Zen Magnets*, 2017 WL 11672449 at *10 (“[T]he concept of ‘foreseeable misuse’ has been an integral part of consumer product safety analysis for more than 40 years, including before the creation of this agency.”). In fact, the Commission has expressly found that it may pursue an action under Section 15 under a defect theory “based *solely* on reasonably foreseeable misuse,” including where consumers were injured because they had

¹¹⁴ Expert Testimony of Umakanth Katwa, April 28, 2023 at 23-24 (Rogal Decl., Exhibit 13).

“disobeyed, did not receive, or did not read [product] warnings.” *Zen Magnets*, 2017 WL 11672449 at *9 (emphasis added), *13.

In this matter, the foreseeable operation and use of the Podster produces a risk of injury to infants. Specifically, the Podster is used for infant sleep by parents and caregivers. Complaint Counsel’s expert witness Celestine Kish has testified concerning the multiple scientific human factors engineering reasons why this is so discussed *supra*. The Podster is also used without constant supervision. Ms. Kish has also presented the scientific literature regarding parental supervision and multi-tasking and explain why constant supervision is not possible with a Podster. When the Podster is used or misused for sleep and without constant supervision, the design defects outlined by Dr. Mannen in her testimony make it possible that an infant may move into a position where the nose and mouth are obstructed, leading to a potential suffocation hazard, and “a risk of injury occurs as a result of the operation or use of the product.” 16 C.F.R. § 1115.4.

3. The Risk of Injury Associated with the Subject Products Renders Them Defective

The factors identified in 16 C.F.R. § 1115.4 also establish that the Podster is defective.

a. Utility of the Product

The Podsters do not offer utility for consumers. As marketed by Leachco, the Podster is supposed to be a place for infants to “loung[e]” while parents or caregivers can attend to other household tasks hands-free. However, because of the risk of an infant sleeping on the Podster or using it without constant supervision, the Podster does not offer utility for a consumer. Instead, as Ms. Kish has testified, there are safe alternatives to the Podster’s intended use, namely CPSC-approved flat, firm cribs, bassinets, and play yards.

Leachco’s own employees tacitly acknowledge the Podster’s lack of utility as an infant

lounging device. [REDACTED]

[REDACTED]

[REDACTED] 115 [REDACTED]

[REDACTED] 116

b. Nature of the Risk of Injury

The nature of the risk of injury is grave. As demonstrated by the testimony of Dr. Katwa, infants placed on the Podster are at risk of suffocation and death. Three infants have died after they were placed on the Podster.

c. Necessity

The Podster may be a comfortable pillow for an infant. However, it is not necessary for an infant to lounge on a Podster. Unlike a knife, which requires a certain level of sharpness to perform a necessary cutting function, as noted above, safer alternatives exist for an infant, including CPSC-approved mattresses, bassinets and play yards.

d. Population Exposed to the Product and Its Risk of Injury

The Subject Products have caused serious life threatening injuries to our most vulnerable population: infants. This population is completely dependent on parents and caregivers to keep them safe. Infants cannot take any care on their own to control their environment while using the Podster to prevent a hazardous scenario in which its mouth or nose is obstructed.

e. Obviousness of the Risk of Injury

Not only do the Subject Products present a serious risk of injury, the nature of that risk is a hidden hazard. Infants obviously cannot comprehend the risk of injury, nor control where they

¹¹⁵ See Exhibit A: Jamie Leach Deposition, March 1, 2023 at 21:8–17.

¹¹⁶ Tonya Barrett Deposition, February 1, 2023 at 27:20–28:12, 29:8–31:11 (Rogal Decl., Exhibit 8).

are placed. And parents and caregivers lack a good understanding of the potential risks. Reasonable parents and caregivers are not likely to appreciate the risks of suffocation and death from a pillow. They may think the infant will react naturally to mouth or nose obstruction with a reflex as an adult would, without understanding that an infant's neural physiology and muscle capacities are entirely different. In summary, the potentially catastrophic risks of the Subject Products are largely hidden to parents and caregivers.

f. Adequacy of Warnings and Instructions to Mitigate Risk

The undisputed serious risk associated with the Subject Products cannot be adequately mitigated through warnings and instructions. The expert testimony from Celestine Kish demonstrated that the warnings and instructions are ineffective at preventing parents and caregivers from using the Podster for sleep. This is primarily because parents and caregivers are motivated to have their infants sleep, they are motivated by social media and media images of infants who use the Podster for sleep, and the Podster does not facially appear hazardous. Ms. Kish also testified that the warnings and instructions are not effective in having parents and caregivers use a Podster with constant supervision. This is primarily due to the fact that perfect parental supervision is impossible—tacitly admitted by Leachco's own marketing materials. Scientific research shows that multi-tasking and working on one task necessarily takes attention away from the task of supervising an infant. The serious risk associated with the Subject Products thus cannot be mitigated through the use of warnings and instructions.

g. Role of Consumer Use and Foreseeability of Such Use

Although the Subject Products are designed for infants to be placed in the supine position on the floor while awake, consumer use behaviors that Respondent may characterize as "misuse" are highly foreseeable. As set forth in additional detail *supra*, parents and caregivers are likely to

use the Podster for sleep and without constant supervision. Accordingly, the use of Podster for these purposes, whether or not the behaviors are appropriately characterized as misuse, is likely and therefore foreseeable.

h. Commission Experience and Expertise

Commission staff has investigated the properties and hazards caused by similar pillow products and inclined sleep products for many years. For more than a decade, Commission staff has been engaged with the evaluation of products for safe sleep for infants. Commission staff has investigated hundreds of reports of injuries and deaths caused by similar products. To address the issues in this Proceeding, Complaint Counsel has relied on its technical staff, and also has engaged experts from crucial disciplines to study and opine on the risks of infant pillows like the Podster. Dr. Erin Mannen, Complaint Counsel’s biomechanical engineering expert, conducted an extensive study of inclined sleep products in 2019 and infant pillows in 2022 for the CPSC. Celestine Kish, an experienced expert on human factors, human engineering, and warnings, has studied how consumers interact with the Podster. Dr. Umakanth Katwa, a board-certified medical doctor and pediatric pulmonologist and sleep specialist, has reviewed the medical consequences to infants that can occur when their breathing is obstructed by the Podster.

i. Case Law

The relevant case law also supports a finding that the Podsters are defective. As explained above, both the Commission and the federal district court in the *Zen Magnets* matter held that the foreseeable use of a consumer product is relevant to the question whether the product is defective. Indeed, the Commission may pursue an action under Section 15 under a defect theory “based solely on reasonably foreseeable misuse,” including where consumers were injured because they had “disobeyed, did not receive, or did not read [product] warnings.” *Zen*

Magnets, 2017 WL 11672449 at *9; *see also Zen Magnets*, 2018 WL 2938326 at *7. Here, expert testimony and common sense establish that the Podsters will be used unsupervised, for sleep, and for bedsharing and so will put their infant occupants at risk of death.

Based on the foregoing, the Subject Products provide limited, if any, utility; are not necessary; and pose a hidden, serious risk to a vulnerable population. Moreover, the risk of injury cannot be mitigated by warnings and any consumer misuse is highly foreseeable. Accordingly, under the factors set forth in 16 C.F.R. § 1115.4, the risk of injury associated with the Subject Products renders the products defective.

C. *The Subject Products Present a Substantial Product Hazard Because They Contain Defects Which, Based on the Patterns of Defect, the Number of Defective Products, and the Severity of the Risk, Create a Substantial Risk of Injury to the Public*

Not only do the Podsters contain a design defect, they present a substantial product hazard within the meaning of Section 15(a)(2) of the CPSA. Under Section 15(a)(2), a substantial product hazard means:

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, the statute sets forth four factors to be considered in determining whether a substantial product hazard exists as the result of a defect which creates a substantial risk of injury: pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise. ***These factors are disjunctive: any one of the factors could create a substantial product hazard.*** 16 C.F.R. § 1115.12(g)(1). Here, all the factors are satisfied, establishing the existence of a substantial product hazard in this case.

Furthermore, Complaint Counsel does not need to show that a certain number of injuries occurred, or a certain ratio of injuries, on the one hand, to products in commerce, on the other, in order to establish that a substantial risk of injury exists. In fact, “the Commission is not required to have evidence of actual injuries in order to address a risk.” *In re Dye*, 1989 WL 435534, *6, *14 (CPSC July 17, 1991) (“With regard to the absence of known fatalities, such evidence is not determinative of whether a product creates a ‘substantial risk of injury to the public’ under section 15. There is no provision in the CPSA that requires proof of actual injuries or deaths in order to show that a product contains a defect that creates a substantial risk of injury to the public.”); *see also In re Zen Magnets*, 2017 WL 11672449 at *20, *36 (finding substantial product hazard despite the existence of only two known injuries with respect to the Subject Products). Nevertheless, there have been three infant deaths after the infants were placed for sleep in the Podsters, and those deaths underscore the dangerous nature of the product.

1. Pattern of Defect

Under 16 C.F.R. § 1115.12(g)(1)(i), the “pattern of defect” analysis requires consideration of whether the defect arises from the “design, composition, contents, construction, finish, packaging, warnings, or instructions of the product . . .” A pattern of defect is established here with respect to the design of the Subject Products, as well as their foreseeable operation and use.

As established above, the Podsters contain design defects that individually and together pose a risk of injury to an infant. Each infant placed in a Podster is exposed to the same design defects inherent in the inclined, overly soft, overly compliant, and insufficiently permeable design of the Podsters, as well as the fact that the Podsters’ design includes high sides that can occlude the nose and mouth of an infant. These design defects result in a risk of injury—

specifically, death through suffocation/asphyxiation—to the uniquely vulnerable infant population. This pattern of defect is present in all Podsters.¹¹⁷

The Podsters also are defective by virtue of their design defects and their operation and use. It is foreseeable that caregivers will use the Podsters unsupervised, for sleep, on elevated surfaces, and in other products. Such operation and use of the products, during which infants' breathing can be compromised by the design defects present in the Podster or by rolling out of the Podster onto other products, also results in a risk of injury—specifically, death through suffocation/asphyxiation—to the uniquely vulnerable infant population.

Thus, the patterns of defect here, which arise from the defects in the physical design of the product and the operation and use of the product, create a substantial risk of injury to the public and therefore present a substantial products hazard under Section 15(a)(2) of the CPSA.

2. Number of Defective Products

Even one defective product can present a substantial risk of injury and provide a basis for a substantial product hazard determination if the injury is serious and/or if the injury is likely to occur. 16 C.F.R. §1115.12(g)(1)(ii).

Leachco admits to selling approximately 180,000 Podsters, meaning that 180,000 products have been distributed in commerce and pose a risk of injury to infants. It is beyond dispute that the injury that can result from the Podsters—death through suffocation—is as serious as an injury can be. Accordingly, the sale of one-hundred eighty thousand infant pillows that can lead to the death of their infant occupants creates a substantial risk of injury to the public and therefore provides a clear basis for a substantial product hazard determination.

¹¹⁷ Expert Testimony of Erin Mannen, Ph.D. at 13 n.5 (Ruff Decl., Exhibit 9).

3. Severity of the Risk

“A risk is severe if the injury which might occur is serious and/or if the injury is likely to occur.” 16 C.F.R. § 1115.12(g)(1)(iii). This factor itself is disjunctive; it can be satisfied with *either* a showing of a serious risk *or* likelihood of an injury. As has been explained above and through Dr. Katwa’s testimony, Complaint Counsel has evidence the injury which might occur is as serious as an injury can be: death. In fact, three infants perished after being placed in Podsters for sleep. Because of this severe risk to infants, the defect creates a substantial risk of injury to the public and, therefore, presents a substantial product hazard.

Although the evidence does not establish that an infant will die each and every time a caregiver uses a Podster, the law does not require a high likelihood of injury to find the existence of a substantial product hazard. A showing that “the injury which might occur is serious” is sufficient, and the evidence establishes that the injury which might occur—death—is serious. One can think of no injury that is more serious.

Together, the pattern of defect, the number of products, and the severity of the risk associated with the Podsters will show by a preponderance of the evidence that the Podsters present a substantial product hazard within the meaning of Section 15(a)(2) of the CPSA.

V. CONCLUSION

Complaint Counsel will prove by a preponderance of the evidence that the Podsters present a substantial product hazard. As detailed above, several aspects of the design of the Podster—such as its inclined and overly soft nature—render the product defective and pose a risk of death to infants. Furthermore, a risk of severe injury—including risk of death—to the

infant population “occurs as a result of the operation or use of the product.” Based on the patterns of defect, the large number of defective products, and the severity of the hidden risk of serious injury to a uniquely vulnerable population, the Podsters create a substantial risk of injury to the public and therefore present a substantial product hazard under section 15(a)(2) of the CPSA. Accordingly, the Court should enter judgment in favor of Complaint Counsel; find that the Podsters constitute a substantial product hazard; and order Leachco to cease the sale and distribution of the Podsters, give public notice, and issue full refunds to consumers.

Dated this 14th day of July, 2023

Respectfully submitted,

/s/ Brett Ruff

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TABLE A: TABLE OF AUTHORITIES

Federal Cases

Concrete Pipe & Products of California, Inc. v. Constr. Laborers Pension Trust for S. California, 508 U.S. 602 (1993)

Steadman v. SEC, 450 U.S. 91 (1981)

In re Winship, 397 U.S. 358 (1970)

Zen Magnets v. CPSC, No. 17-cv-02645-RBJ, 2018 WL 2938326 (D. Colo. June 12, 2018)

Federal Statutes

5 U.S.C. § 554

5 U.S.C. § 556

15 U.S.C. § 2052

15 U.S.C. § 2064

Federal Regulations

16 C.F.R. § 1025.22

16 C.F.R. § 1025.51

16 C.F.R. § 1115.4

16 C.F.R. § 1115.12

Commission Decisions

In re Dye, 1989 WL 435534 (CPSC July 17, 1991)

In re Zen Magnets, 2017 WL 11672449 (CPSC October 26, 2017)

EXHIBIT A

(Submitted *in camera*)