UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

COMPLAINT COUNSEL'S POST-HEARING BRIEF

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Pursuant to 16 C.F.R. § 1025.46 and the Court's August 10, 2023 order during the hearing, Complaint Counsel hereby submits this Post-Hearing Brief containing proposed findings of fact, conclusions of law and a proposed Order.

I. INTRODUCTION

At the hearing, Complaint Counsel proved by a preponderance of the evidence that the Podster infant 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"). Complaint Counsel's case was established by its testifying expert witnesses including its biomechanical engineering expert, Dr. Erin Mannen, its human factors engineering expert, Ms. Celestine Kish, and its medical expert, Dr. Umakanth Katwa. All of those witnesses credibly supported Complaint Counsel's claim showing all models of Leachco Podster infant pillows ("Podsters") 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, compressible, 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. Further, the risk of injury posed by the Podsters also renders the products defective. *See id.*

None of Leachco's evidence refuted Complaint Counsel's well-supported claims or warrants a ruling in their favor. Thus, because the evidence established that the Podster creates a substantial product hazard, Complaint Counsel respectfully requests the Court issue an initial

decision pursuant to 16 C.F.R. § 1025.51 adopting the proposed findings of fact and conclusions of law herein, and issue the proposed Order attached hereto at Exhibit A.

II. PROPOSED FINDINGS OF FACT

A. Respondent Leachco, Inc.

Leachco is an Oklahoma corporation founded in 1988 by Jamie Leach and Clyde Leach.[1] Leachco manufactures, distributes, and offers for sale more than 90 products, including pillows for infants, children, and adults.[2] Leachco markets and sells its products through its website www.leachco.com, as well as throughout the United States through retailers.[3]

Jamie Leach is Leachco's Vice President and Chief of Product Development.[4] She is also a nurse, who last practiced full-time nursing in or about 1988.[5] Ms. Leach designed Leachco's products, including the Podster.[6] Clyde Leach is Leachco's President and Chief Executive Officer.[7] Leachco has approximately 30 employees and is located in Ada, Oklahoma.[8]

Leachco has generated [redacted] in revenues from the sale of its various products. In 2022, Leachco's revenues were approximately [redacted].[9] In 2021, Leachco's revenues were approximately [redacted].[10] Of the more than 90 products it sells, Leachco's top selling products include the Snoogle body pillow for adults and the Cuddle-U nursing pillow.[11] The Podster is not currently, nor has it ever been, one of Leachco's top

[1] JX-51 (Joint Stipulations) at 1, ¶ 1.
[2] *Id.* ¶ 2.
[3] *Id.* ¶ 3, 4.
[4] *Id.* ¶ 5; August 8, 2023 Hearing Transcript, 111:9-11.
[5] August 8, 2023 Hearing Transcript, 112:7-113:1.
[6] JX-51 (Joint Stipulations) at 1, ¶ 6; August 8, 2023 Hearing Transcript 111:20-21.
[7] JX-51 (Joint Stipulations) at 1, ¶ 7; CCX-5A (Excerpts from Clyde Leach Deposition, February 28, 2023), 33:4-8.
[8] JX-51 (Joint Stipulations), at 1, ¶ 8.
[9] CCX-5A (Excerpts from Clyde Leach Deposition, February 28, 2023), 88:21-89:8. According to information provided by Leachco's Controller after the hearing, revenue in calendar year 2022 was [redacted].
[10] *Id.* at 88:21-89:4. According to certain tax documents provided by Leachco after the hearing, the firm has [redacted] in revenues in 2021.
[11] JX-51 (Joint Stipulations) at 1, ¶ 2; CCX-5A (Excerpts from Clyde Leach Deposition, February 28, 2023), 99:10-104:7; August 8, 2023 Hearing Transcript, 151:11-20.

selling products.[12]

B. *The Leachco Podster*

The products at issue here are various models of the "Podster" infant lounging pillows, including the Podster, Podster Plush, Bummzie, and Podster Playtime models.[13] The Podsters are manufactured in Leachco's facilities in Ada, Oklahoma.[14] The Podsters are distributed and offered for sale to consumers for their personal use.[15] Since 2009, Leachco has manufactured and distributed approximately 180,000 Podsters.[16]

Leachco sold the Podster for a retail price ranging from $49 and $89.[17] The Leachco website describes the Podster as follows: "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."[18] Leachco's website further describes the purported benefits of the product as follows: "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

[12] CCX-5A (Excerpts from Clyde Leach Deposition, February 28, 2023), 104:7-105:7; August 8, 2023 Hearing Transcript, 152:4-8.

[13] JX-51 (Joint Stipulations) at 1-2, ¶ 9; JX-14 (Answer), ¶ 7, 9. Dr. Mannen testified that each of the models were substantially similar. CCX-1 at 13 n.5.

[14] JX-51 (Joint Stipulations) at 2, ¶ 10; JX-14 (Answer) ¶ 8.
[15] JX-51 (Joint Stipulations) at 2, ¶ 11; JX-14 (Answer) ¶ 7.
[16] JX-51 (Joint Stipulations) at 2, ¶ 13; JX-14 (Answer) ¶ 10.
[17] JX-51 (Joint Stipulations) at 2, ¶ 14; JX-14 (Answer) ¶ 10.
[18] JX-51 (Joint Stipulations) at 2, ¶ 16.

help aid in digestion and breathing."[19]

Prior to selling the Podster, Leachco did not conduct any safety testing to assess whether the product posed a suffocation hazard.[20] Leachco did conduct certain tests on the Podster, including testing for lead and sharp edges; however, Leachco never performed any tests designed to determine whether the Podster posed a potentially fatal suffocation hazard for infants, including testing the Podster's incline angles, firmness, airflow, infant positioning, or carbon dioxide rebreathing levels, even after receiving reports of infants suffocating in the product.[21]

C. *The Podster's Design Defects*

At the hearing, Dr. Erin Mannen, Complaint Counsel's biomechanical engineering expert, testified that the Podster presents several design defects that create a suffocation hazard. Dr. Mannen testified that she tested 10 Podsters, 5 standard style and 5 plush style.[22] During the hearing, Dr. Mannen illustrated her testing on two physical samples of the Podster that were admitted into evidence.[23] Dr. Mannen explained that the Podster is defective for the following reasons:

- **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.[24]
- **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

[19] *Id.* ¶ 15; JX-30 (Podster Product Description from Leachco.com).
[20] August 8, 2023 Hearing Transcript, 141:8-142:4.
[21] *Id.* at 140:19-142:4; CCX-5A (Clyde Leach Deposition Excerpts, February 28, 2023) at 116:2-121:6.
[22] August 7, 2023 Hearing Transcript, 46:1-4.
[23] JX-1 (Podster sample 21-800-2297-03, standard model); JX-2 (Podster sample 22-800-1417-05, plush model).
[24] CCX-1 (Expert Testimony of Erin Mannen, Ph.D., April 28, 2023) at 6, 48-49; CCX-52 (Airflow Testing on the Podster Video).

obstructed by the Podster;[25]

- **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;[26]
- **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;[27]
- **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;[28]
- **Positional Asphyxia**. Its shape and design causes increased flexion that inhibits breathing and enables an infant to slide down into the seat of the product, causing further increased flexion that further inhibits breathing;[29] 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.[30]

Further, Dr. Mannen's expert testimony presented specific conclusions regarding hazards posed by certain characteristics of the Podster, including incline angles, firmness, airflow, infant positioning, and carbon dioxide rebreathing levels, based on her scientifically valid testing and analysis of the Podsters:

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[25] *Id.* at 21-24, 46-48; CCX-50 (Firmness Testing on the Podster with Disk Testing Device Video); CCX-51 (Firmness Testing on the Podster with Vertical Lifter Testing Device).
[26] CCX-1 (Expert Testimony of Erin Mannen, Ph.D., April 28, 2023) at 41-43.
[27] *Id.*
[28] *Id.*; CCX-56 (Body Position on the Podster Facilitating Rolling Video).
[29] CCX-1 (Expert Testimony of Erin Mannen, Ph.D., April 28, 2023) at 18 n.10, 36-40; CCX-45 (Movement from the Intended to the Slouched Position on the Podster Video); CCX-46 (Testing for Trunk and Hip Flexion in the Intended Position on the Podster Video); CCX-47 (Testing for Trunk and Hip Flexion in the Slouched Position on the Podster Video).
[30] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 63-64.

- **Incline angles**. Dr. Mannen's testimony explained that the inclined nature of the Podster presents certain hazards related to how the infant sits and how that affects the infant's breathing.[31] Dr. Mannen's finding was that the head and thigh angles of the Podster are similar to dangerous inclined sleep products.[32] 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.[33]
- **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.[34] 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.[35]
- **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.[36]
- **Firmness**. Dr. Mannen's expert testimony detailed 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

[31] *Id.* at 32-34.
[32] *Id.* at 32.
[33] *Id.* at 32-34.
[34] *Id.* at 41-43.
[35] *Id.*
[36] *Id.* at 44-46.

difficult.[37] 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."[38]

- **Airflow**. Dr. Mannen's expert testimony contained data and analysis of airflow testing of the Podster that demonstrate the negative effects on an infant's breathing when interacting with the product.[39] Dr. Mannen's main finding was that Podsters "exhibited *over 10 times less airflow* . . . compared to the recommended threshold."[40]
- **Infant Positioning**. Dr. Mannen's expert testimony outlined 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 or otherwise had slid down into the recessed portion of the pillow."[41] 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 CO_2 inhalation."[42]
- **Carbon-Dioxide Rebreathing**. Dr. Mannen also presented her data and analysis regarding CO_2 rebreathing.[43] The main conclusion there is that the Leachco Podster demonstrated an increase of nearly 2.5 times the amount of CO_2 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 "O_2 decreases and the CO_2 substantially increases, increasing the risk for hypoxia (not breathing enough oxygen)

[37] *Id.* at 46-48.
[38] *Id.* at 47 (emphasis in original).
[39] *Id.* at 48-49.
[40] *Id.* at 48 (emphasis in original).
[41] *Id.* at 52.
[42] *Id.* at 53.
[43] *Id.* at 49-51.

and breathing in too much CO_2."[44]

As a result of these defects, and based on her testing and evaluation of the Podsters, Dr. Mannen testified that the Podsters pose asphyxiation and suffocation hazards for infants. Specifically, Dr. Mannen's expert opinions can be summarized as follows:

- The Podster's design causes a flexed head/neck and flexed trunk posture during supine lying, inhibiting normal breathing;
- The Podster's design facilitates some types of rolling on or off of the product, introducing concerning suffocation-related risks for the infant;
- The Podster increases abdominal fatigue if an infant finds themselves prone in the pillow, increasing the risk of suffocation;
- The Podster negatively affects the ability of an infant to self-rescue from the prone position to a safe breathing position;
- 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,
- The Podster negatively affects the ability of an infant to breathe normally if they are prone or side-facing in the product.[45]

D. Foreseeable 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.[46] Leachco instructs that parents and caregivers should use the Podster on the floor with an awake infant and constantly supervise the infant.[47]

Despite Leachco's warnings and instructions, caregivers foreseeably use the Podster for infant sleep.[48] There are several reasons why this occurs. First, parents and caregivers are

[44] *Id*. at 49-50.
[45] CCX-1 (Expert Testimony of Erin Mannen, Ph.D., April 28, 2023) at 5-6.
[46] JX-51 (Joint Stipulations) at 2-3, ¶ 17, 19; JX-14 (Answer), ¶¶ 13-14.
[47] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 60, ¶ 117.
[48] *Id.* at 60-61, ¶¶ 118-119; August 8, 2023 Hearing Transcript, 24:4-11.

motivated to have infants under their care fall and stay asleep for extended periods of time. If that sleep can be achieved on the Podster, parents and caregivers may permit infants to sleep in it.[49] Even Leachco's own employees testified during depositions that they and their relatives have used the Podster for infant sleep.[50] 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."[51] Jamie Leach even conceded that "you can't control where babies choose to go to sleep."[52]

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. And, current safe sleep recommendations are often ignored by parents and caregivers in the face of counter-examples that depict unsafe behaviors.[53] 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 consumers to disregard the warnings and use the Podster for sleep.[54] Celestine Kish, a CPSC staff engineering psychologist with over three decades of experience in the field of consumer product safety, especially infant products like the Podster, provided various real-life examples in her expert testimony where the Podster

[49] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 60, ¶ 118.
[50] *Id.* at 73-74, ¶¶ 145-46; CCX-42 (Mabry Ballard Deposition, January 31, 2023) at 180:15–19; CCX-43 (Tonya Barrett Deposition, February 1, 2023) at 27:20–28:12, 29:8–30:9.
[51] JX-46 (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)).
[52] August 8, 2023 Hearing Transcript, 127:2-7.
[53] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 37-42, ¶¶ 72-82.
[54] *Id.* at 42-56, ¶¶ 83-108; JX-46 at 5 (Leachco's Second Supplemental Response to CPSC RFA Nos. 3, 4, & 5, March 13, 2023 at 5 (second supplemental response to RFA No. 5) (admitting that Leachco "had knowledge that there were reviews on Amazon.com that referenced infants sleeping on Podsters")).

was being used for sleep by parents or caregivers.[55] Indeed, Leachco's own official Instagram account has "liked" photographs of infants sleeping on Podsters, and one example of such was admitted into evidence during the Hearing.[56]

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.[57]

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.[58]

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.[59]

Finally, and 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 these, the infant was placed in the Podster for sleep before the fatal incident.[60]

E. Foreseeable Consumer Use of the Podster Without Constant Supervision

Leachco's warnings require "constant adult supervision" but also claim an adult can multitask hands-free while an infant is in the Podster—meaning a caregiver may engage in

[55] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 42-56, ¶¶ 83-108.
[56] CCX-59.
[57] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 62, ¶ 121.
[58] *Id.* at 4-5, ¶ 4.
[59] *Id.* at 63-64, ¶¶ 124-25.
[60] *Id.* at 70-72, ¶¶ 137-144; CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 26–29; *see also* JX-45 (Leachco's Objections and Responses to CPSC First Set of Requests for Admission, November 30, 2022 at 3-4 (Response to RFA No. 6)).

activities like "prepare a meal, pay bills, check email, give a hand to siblings and many other daily tasks."[61] Yet by engaging in these other household activities, it is foreseeable that a parent or caregiver necessarily is taking attention away from supervising the infant in the Podster—and thus is unable to supervise constantly.[62] Consumers are not likely to appreciate that infants can roll or move into a compromised position, will be unable to self-rescue, and can suffocate or asphyxiate within minutes when placed unsupervised on a Podster.[63] The Podster's design provides a false sense of security to caregivers that an infant can be safely left unsupervised.[64] Scientific research demonstrates—and common sense supports—that as Leachco advances is possible with the Podster—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.[65] Lapses in supervision when using a Podster—which are inevitable despite Leachco's warnings and instructions—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.[66]

F. Foreseeable 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.

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[61] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 66, ¶ 130; JX-51 (Joint Stipulations) at 2, ¶ 16.
[62] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 66, ¶ 130.
[63] *Id.* at 65, ¶ 129.
[64] *Id.*
[65] *Id.* at 66, ¶ 130. At the hearing, Leachco's expert, Peggy Shibata claimed a parent could be both supervise an infant in the Podster and attend to other tasks, but this testimony should not be accorded any weight because Ms. Shibata provided no authorities or research supporting her view. August 10, 2023 Hearing Transcript, 28:12-36:7.
[66] *Id.* at 66 n.121. Leachco's expert, Peggy Shibata, does not contradict or address these safe alternatives in her testimony. RX-1 (Expert Testimony of Peggy Shibata, April 28, 2023) at 14. Ms. Shibata also admitted during cross examination that safe alternatives existed in place of using a Podster. August 10, 2023 Hearing Transcript, 37:11-38:19.

Bedsharing, sometimes referred to as "co-sleeping," poses a suffocation hazard because adults 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 testimony at the hearing that the design of the Podster can cause an infant to roll off of it and onto an adult bed.[72]

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.[73] Nevertheless, caregivers may use the Podster on elevated surfaces.[74] 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.[75]

It also is foreseeable that caregivers will place infants on Podsters that are themselves

[67] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 63-65, ¶¶ 124-28.
[68] *Id*.
[69] *Id.*
[70] *Id.*
[71] *Id*. at 64, ¶ 126.
[72] August 7, 2023 Hearing Transcript, 70:6-71:2, 141:15-22; JX-8 (TX IDI redacted); JX-9 (TX IDI unredacted).
[73] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 63-65, ¶¶ 124-28.
[74] *Id.*
[75] *Id.*

contained within another product, such as a crib or play yard. The use of the Podster in a crib or similar sleep product creates yet another safety hazard—entrapment—which can lead to suffocation.[76] If 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.[77] In addition, if the Podster is used on a bed or couch, an infant can roll off the product and become entrapped in the environment (e.g., between the mattress and headboard, or between couch cushions).[78] 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.[79]

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

At the hearing, Complaint Counsel proved that the Podster presents several scenarios that can cause severe injury or death to an infant. First, Dr. Umakanth Katwa, Complaint Counsel's medical expert, a lecturer at Harvard Medical School and an attending physician in the Division of Pulmonary Medicine at Boston Children's Hospital, testified that even in the intended supine position, an infant can suffer from neck flexion due to the inclined and compressible design of the Podster.[80] 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.[81] As a result, if the infant's airway is blocked or collapsed, air cannot enter the lungs, which can result in progressive and severe hypoxemia, cardiorespiratory arrest, and death.[82]

Second, the Podster's inclined, soft, and compressible design facilitates infant

[76] *Id*. at 65, ¶ 128.
[77] *Id*.
[78] *Id*.
[79] *Id*.
[80] CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 10.
[81] *Id.* at 10-11.
[82] *Id.* at 11.

movement.[83] Infants can move into a slouched position and be at risk of positional asphyxia, even in the supine position.[84] Dr. Katwa testified at the hearing that the slouched position creates abdominal pressure, which negatively affects the diaphragm, and also creates muscle fatigue. Neck flexion in the slouched position also creates a risk of airway compression like in the intended position.[85] Airway compression and obstructive breathing caused by this position can lead to prolonged hypoxemia, increased carbon dioxide inhalation, unconsciousness, and death.[86]

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.[87] 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.[88] Infants who move into a hazardous position have difficulty self-rescuing because they do not have the strength to move out of the dangerous position.[89] 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.[90] 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.[91]

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, rolls into, or is placed in a prone position, the medical evidence detailed by Dr. Katwa's testimony demonstrates that

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[83] *Id.* at 4.
[84] *Id.* at 20.
[85] *Id.* at 21.
[86] *Id.*
[87] *Id.*
[88] *Id.* at 4.
[89] *Id.* at 19.
[90] *Id.* at 21.
[91] *Id.* at 14.

infants can suffer from suffocation, asphyxiation, or death within minutes.[92] The risk of severe injury or death was also confirmed by Dr. Katwa's review of the fatal incidents involving infants placed in a Podster for sleep in Alabama, Texas, and Virginia.[93] Dr. Katwa also explained at the hearing the impact of the AAP "Back to Sleep" recommendations that recommended babies be placed on their backs in a flat, firm, sleep surface—not in products like the Podster—and how those recommendations dramatically reduced the incidents of infant suffocation from SIDS.[94]

H. Fatal Incidents Illustrate the Deadly Risk of Suffocation Posed by the Podster

Tragically, in this case there have been three reported incidents of infant deaths associated with the use of the Podster. At the hearing, Complaint Counsel provided evidence of the incidents through witness testimony and presenting CPSC's In-Depth Investigations ("IDIs"), which were admitted into evidence.[95] In each of the these, the infant was placed in the Podster for sleep before the fatal incident.[96] These incidents resulted in fatalities to infants, a uniquely

[92] *Id.* at 25-26.
[93] *Id.* at 26-29. 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* RX-01 (Expert Testimony of Peggy Shibata, April 28, 2023) at 5-7.
[94] August 9, 2023 Hearing Transcript, August 9, 2023 at 29:9-31:14; *see also* RX-37 at 1 (AAP Sleep-Related Infant Deaths Updated Recommendations); (RX-03 at 1-3 (NIH Safe Sleep Recommendations).
[95] August 7, 2023 Hearing Transcript, 173:15-206:18; JX-10 (Virginia incident IDI redacted); JX-11 (Virginia incident IDI unredacted); August 8, 2023 Hearing Transcript, 7:3-10:9; JX-6 (Alabama incident IDI redacted); JX-7 (Alabama incident IDI unredacted); JX-8 (Texas incident IDI redacted); JX-9 (Texas incident IDI unredacted); *see also* JX-12A and JX-12B (MECAPS Report Virginia Incident, redacted and unredacted versions).
During the course of the hearing, the Presiding Officer admitted the IDIs that CPSC Product Safety Investigators ("PSIs") compiled and prepared with respect to the three fatal incidents involving Leachco Podsters. Those records were correctly ruled as admissible, as records of regularly conducted activity and public records under Federal Rule of Evidence 803(6) and 803(8), respectively. *See, e.g.*, *Schulman v. Saloon Beverage Inc.*, Civ. Action. No. 2:12-CV-193, 2014 WL 3353254, at *6 (D. Vt. July 9, 2014) ("Generally, a police report may be admissible as a business or public record under Fed.R.Evid. 803(6) or 803(8)."); *Harrell v. Fibreboard Corp.,* Civ. A. No. 85-4604, 1989 WL 145810, at *8 (E.D. Pa. Nov. 27, 1989) ("Rule 803(6), the business records exception to the hearsay rule, makes admissible contemporaneously recorded opinions and diagnoses in medical reports that are kept in the course of a regularly conducted business activity."). The IDIs also contain the factual findings of the CPSC PSIs who conducted investigations that were legally authorized under the CPSA. Such "factual findings from a legally authorized investigation" are expressly admissible under Rule 803(8)(A)(iii) of the Federal Rules of Evidence. *See also Beech Aircraft Co. v. Rainey*, 488 U.S. 153, 160 (1988) (FRE 803(8)(A)(iii) "excepts investigatory reports from the hearsay rule."). Additionally, the IDIs properly were relied on by each of CPSC's three experts in reaching their expert opinions and preparing their expert testimony. As Federal Rule of Evidence 703 provides, materials need not be admissible in order for an expert witness to review or rely upon them. Given the credibility of these records, the Court should afford the IDIs significant weight when making its findings of fact and conclusions of law.
[96] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 70-72, ¶¶ 137-144; CCX-3 (Expert Testimony of

vulnerable population. Each of the three incidents also involved foreseeable use of the Podster discussed above; both unsupervised use and for sleep. And in each instance, the Podster was placed on or within another object or surface (a crib, an adult bed, and a playpen) to allow the infant to sleep. In the Alabama incident, and as detailed in the IDI, Dr. Katwa testified that the infant was placed to sleep in a Podster located 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.[97] In the Texas incident, and as detailed in the IDI, Dr. Katwa testified that an infant was placed to sleep on a Podster and 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.[98] In the Virginia incident, and as detailed in the IDI, Dr. Katwa testified that an infant was placed to sleep in a Podster located 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 suffocation, even in the side position of the Podster where the infant was found.[99] Thus, Dr. Katwa found—as confirmed in all the IDIs—that in all three infant deaths, the incidents were associated with use of a Podster in a foreseeable manner, unsupervised and for sleep, which contributed to risk of death.

III. PROPOSED CONCLUSIONS OF LAW

A. Complaint Counsel Proved its Case at the Hearing By a Preponderance of the Evidence

The record supports that Complaint Counsel proved its case in chief by a preponderance

Umakanth Katwa, April 28, 2023) at 26–29; *see also* JX-45 (Leachco's Objections and Responses to CPSC First Set of Requests for Admission, November 30, 2022) at 3-4 (Response to RFA No. 6).

[97] CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 26-27.

[98] *Id.* at 27.

[99] *Id.* at 28–29.

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).

As further detailed below, Complaint Counsel satisfied this standard.

B. *The Podsters Present 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). Further, in determining whether a risk of injury itself 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 Podsters contain design defects which create a substantial risk of injury to the public, and because the risk of injury renders the Podsters defective, the Podsters 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 Podsters and implement a corrective

action, including a recall and public notice of the recall. *See* Exhibit A.

1. The Podsters 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, and Dr. Katwa elaborated on the medical consequences of such defects. Standing alone, any one of the design defects renders the Podster defective. Together, they create a grave 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.[100] 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.[101] 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.[102]
- **The Podsters Facilitate Rolling**. Dr. Mannen concluded that the Podster's design facilitates rolling within or off of the product, which can lead to the mouth and nose of the infant becoming obstructed.[103] Dr. Mannen contrasted the Podster's mechanical environment with that of a firm, flat surface and determined that the

[100] CCX-1 (Expert Testimony of Erin Mannen, April 28, 2023) at 32-34.
[101] CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 30.
[102] CCX-1 (Expert Testimony of Erin Mannen, April 28, 2023) at 18 n.10; CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 21-22, 30.
[103] CCX-1 (Expert Testimony of Erin Mannen, April 28, 2023) at 42.

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.[104] 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."[105]

- **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 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.[106] 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.[107]

- **The Podsters' Lack of Firmness Creates a Risk of Suffocation**. Dr. Mannen testified that the Podsters are substantially softer than a crib mattress.[108] As Dr.

[104] *Id.*
[105] CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 30.
[106] CCX-1 (Expert Testimony of Erin Mannen, April 28, 2023) at 44-46.
[107] CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 30.
[108] CCX-1 (Expert Testimony of Erin Mannen, April 28, 2023) at 47.

Katwa testified: "[t]his increases the risk for suffocation and rebreathing when infants roll over to the prone or side sleeping position."[109] 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."[110]

- **The Podsters Place Infants in Positions Where Their Breathing Can Be Compromised.** Dr. Mannen testified 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 recessed portion of the pillow."[111] 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 CO_2 inhalation."[112]
- **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."[113] Dr. Mannen also presented data and analysis regarding CO_2 rebreathing.[114] The main conclusion is that the design of the Podster causes an

[109] CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 19.
[110] *Id.*
[111] CCX-1 (Expert Testimony of Erin Mannen, April 28, 2023) at 52.
[112] *Id.* at 53.
[113] *Id.* at 48 (emphasis in original).
[114] *Id.* at 49-51.

increase of nearly 2.5 times the amount of CO_2 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 "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."[115] Dr. Katwa, in turn, evaluated this restricted airflow and elevated CO_2 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. 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.[116]

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

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

A design defect may also be present if a risk of injury occurs as a result of the operation

[115] *Id*. at 49-50.
[116] CCX-3 (Expert Testimony of Umakanth Katwa, April 28, 2023) at 23-24.

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 regulation also explicitly states that 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, at *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 "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, as advertised by Leachco as a hands-free tool to help parents multi-task, 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 testified at the hearing 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 scientific literature regarding parental supervision and multi-tasking and explained why constant supervision is not possible with a Podster. When the Podster is used for sleep and without constant supervision—both foreseeable uses of the

Podsters—the design defects outlined by Dr. Mannen in her testimony make it possible that an infant may move into a compromised position, leading to a potential suffocation or asphyxiation hazard. Thus, the Podsters are defective because "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 Podsters Renders the Podsters Defective

Additionally, pursuant to 16 C.F.R. § 1115.4, the risk of injury posed by a product may render the product defective. "Section 1115.4 provides a great deal of flexibility in interpreting 'defect' in Section 15(a)(2) of the CPSA. Because of the breadth of consumer products that fall within the Commission's jurisdiction and the range of product characteristics that could present a defect, the Commission's defect analysis must be very flexible and must take relevant factors into consideration, as appropriately applied to the fact-specific circumstances of each case. See Interpretation, Policy, and Procedure for Substantial Product Hazards, 43 Fed. Reg. 34,988, 34,991 (Aug. 7, 1978) ("1978 Final Rule") (stating that the Commission conducts defect determinations on a case-by-case basis and 'interprets the term defect as used in Section 15(b) to include the broadest meaning found in Federal and State statutes and judicial pronouncements')." *Zen Magnets*, 2017 WL 11672449 at *8. "In determining whether the risk of injury associated with a product is the type of risk which will render the product defective," the Commission considers the following factors listed below. 16 C.F.R. § 1115.4. Consideration of these factors also establish that the Podster is defective.

a. Utility of the Product

The Podsters do not offer utility for consumers. The Podster is marketed as a place for infants to "lounge" while parents or caregivers can attend to other household tasks hands-free. In other words, Leachco urges parents to purchase the product because it will give them an

opportunity to turn their attention to other tasks while the infant is resting in the product. A resting newborn or infant who is tired or has been fed and then placed in a soft bed-like surrounding, will, in all likelihood, fall asleep unless actively engaged by a caregiver. That type of parental interaction is directly contrary to the advertised purpose of the Podster: the product's marketing advances a use that cannot in all practicality be achieved. Even the founder of Leachco and the designer of the Podster, Jamie Leach, admitted during cross-examination that infants falling asleep in the product or use of the product without constant supervision could not be controlled—supporting Complaint Counsel's theory that the Podster does not offer utility but instead poses a deadly risk for infants.[117]

Moreover, Leachco's own employees tacitly acknowledged the Podster's lack of utility as an infant lounging device. The designer of the Podster, Jamie Leach, has never used the product with her own human family, but, instead, only has used the product as a dog bed for a Yorkshire Terrier.[118] And Leachco's Compliance Specialist converted a Podster to a dog bed after she learned that her daughter-in-law repeatedly had allowed her grandchild to sleep in a Podster.[119]

b. Nature of the Risk of Injury

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

c. Necessity

The Podster is not a necessity but rather a novel product marketed as a substitute for a safe place for infants. Unlike a knife, which requires a certain level of sharpness to perform a

[117] August 8, 2023 Hearing Transcript, 127:2-7.
[118] August 8, 2023 Hearing Transcript, 125:3-17.
[119] CCX-43 at 5-8 (Tonya Barrett Deposition, February 1, 2023 at 27:20–28:12, 29:8–31:11).

necessary cutting function, *see* 16 C.F.R. § 1115.4, at the hearing Complaint Counsel showed that safer alternatives exist for an infant to be placed when not being held, including CPSC-approved mattresses, bassinets and play yards.[120] Further, despite certain unverified claims made by Leachco regarding aiding in breathing and digestion, there is no need to use the Podster to assist in those functions. In fact, testimony provided by Drs. Mannen and Katwa shows that—quite to the contrary—the Podster does not aid in digestion and makes breathing more difficult and compromised.[121] The Podster has only been sold since 2009 and there is no evidence that the Podster was necessary for parents or caregivers prior to 2009 or during the time it was distributed. Leachco's own expert even testified that there are safe alternatives to the Podster; thus, essentially confirming that using the Podster is not necessary when caring for an infant. Therefore, the Podster is not a necessity and consumers can care for infants without using the product.

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

The Podsters are marketed expressly for use with infants, and have caused three deaths to its intended users. Infants are unable to prevent a hazardous scenario in which their mouths or noses are obstructed by a Podster. Ms. Kish testified that caregivers cannot provide constant and perfectly attentive supervision of an infant on a Podster, and as infants develop they become more able to move into a compromised position.[122] She also testified that it is likely that the Podsters will be used for sleep.[123] Dr. Mannen testified that the Podster's design facilitates movement into potentially compromised positions and negatively affects an infant's ability to

[120] August 8, 2023 Hearing Transcript, 27:20-28:19. Leachco's expert admitted under cross examination that safe alternatives existed in place of the Podster. August 10, 2023 Hearing Transcript, 38:2-19.
[121] CCX-1 at 6; CCX-3 at 29-30.
[122] CCX-2 at 66-67, ¶¶ 131-32.
[123] CCX-2 at 54-55, ¶ 111.

self-rescue from a position in which the nose and mouth are obstructed. Further, Dr. Katwa testified about infants' immature respiratory system and how vulnerable they are during sleep, including REM sleep.[124] Thus, infants are even more helpless when placed in a Podster for sleep or when they are not supervised.[125]

e. Obviousness of the Risk of Injury

Not only do the Podsters present a serious risk of injury, the nature of that risk is a hidden hazard. The Podster is marketed by Leachco as a place for newborns and infants to "lounge," and consumers presume that using the Podster, a product marketed directly for newborns and infants, would not be dangerous. However, parents and caregivers lack a good understanding of the potential risks and that their foreseeable uses could lead to deadly consequences. Reasonable parents and caregivers are not likely to appreciate the risks of suffocation, asphyxiation, and death from a product marketed specifically for newborns and infants. 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, or without understanding, as Dr. Katwa testified, "it can take as little as 2 to 3 minutes for an infant to become non-responsive due to suffocation."[126] Additionally, they may not even expect that a product for lounging can create such a hazardous and deadly scenario. Further, unsuspecting parents and caregivers may not even be aware that seemingly innocuous and foreseeable use of the Podster for sleep or while multi-tasking could lead to fatal outcomes within the space of a few minutes. This is further supported by Ms. Kish's testimony regarding social media and counter-examples, which may give consumers comfort in using the Podster in a foreseeable

[124] CCX-3 at 7, 14-16.
[125] CCX-1 at 44-46.
[126] CCX-3 at 4.

manner, not realizing the potentially deadly consequences.[127] In summary, the potentially catastrophic risks of the Podsters are largely hidden to parents and caregivers.

f. Adequacy of Warnings and Instructions to Mitigate Risk

The undisputed serious risk associated with the Podsters 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 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 ensuring that parents and caregivers will only use a Podster with constant supervision. Perfect parental supervision is impossible—tacitly admitted by Leachco's own marketing materials. Scientific research shows that multi-tasking necessarily takes attention away from the task of supervising an infant. The deadly risk associated with the Podsters cannot thus be mitigated through warnings and instructions.

g. Role of Consumer Use and Foreseeability of Such Use

Although the Podsters 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 Ms. Kish testified, it is foreseeable that parents and caregivers will use the Podster for sleep because they are motivated to have infants under their care fall and stay asleep for extended periods of time. Even Leachco's own employees testified during depositions that they and their relatives have used the Podster for infant sleep,[128] and Jamie Leach even conceded

[127] CCX-2 at 39-53, ¶¶ 83-108.
[128] *Id.* at 73-74, ¶¶ 145-46; CCX-42 (Mabry Ballard Deposition, January 31, 2023) at 180:15–19; CCX-43 (Tonya Barrett Deposition, February 1, 2023) at 27:20–28:12, 29:8–30:9.

that "you can't control where babies choose to go to sleep."[129] It is also foreseeable that the Podster will be used for sleep because many parents and caregivers are influenced by social media and other images showing infants sleeping on the Podster. Ms. Kish testified that safe sleep recommendations are often ignored by parents and caregivers in the face of counter-examples that depict unsafe behaviors.[130] Indeed, Leachco's own official Instagram account has "liked" photographs of infants sleeping on Podsters, and one example of such was admitted into evidence during the Hearing.[131]

It is also foreseeable that a parent or caregiver will use the Podster without constant supervision, because as Ms. Kish testified, consumers are not likely to appreciate that infants can roll or move into a compromised position, will be unable to self-rescue, and can suffocate or asphyxiate within minutes when placed unsupervised on a Podster.[132] Leachco itself markets the Podster to be used when multi-tasking, necessarily meaning that consumers will not be able to constantly supervise an infant while doing such other activities. Also, 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. This is because as Ms. Kish testified, the Podster may be an attractive option as it is soft, portable, and can easily be brought into the bed.[133]

Accordingly, it is highly foreseeable that the Podsters will be used by consumers for sleep and for unsupervised use. Although Leachco may characterize these behaviors as misuse, Complaint Counsel's evidence establishes that such use is foreseeable, and that evidence is

[129] August 8, 2023 Hearing Transcript, 127:2-7.
[130] CCX-2 (Expert Testimony of Celestine Kish, May 2, 2023) at 37-42, ¶¶ 72-82.
[131] CCX-59.
[132] *Id.* at 65, ¶ 129.
[133] *Id*.

supported by Leachco's own employees who have used the product in such manners, the company's official Instagram account has endorsed consumers using the product for sleep by liking posts of babies sleeping in the Podster, and its own founder and Podster developer noted one cannot control where babies sleep.

h. Commission Experience and Expertise

For more than a decade, Commission staff has investigated the properties and hazards of products for safe sleep for infants. The Commission, public safety agency charged with protecting the public from unreasonable risks of injury associated with consumer products, 15 U.S.C. § 2051(b)(1), has long advocated for safe sleep practices as recommended by the American Academy of Pediatrics.[134] Commission staff has investigated and analyzed hundreds of reports of injuries and deaths caused by inclined sleep products and similar pillows. 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 inclined sleep products and pillows similar to 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, and her experience has led to important recalls, such as more than 3 million Boppy infant pillows in September 2021—which share characteristics with the Podster.[135] 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, pediatric pulmonologist, and sleep specialist,

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[134] *See* https://www.cpsc.gov/Newsroom/News-Releases/2011/A-Safe-Sleep-For-All-BabiesCPSC-and-Child-Safety-Partners-Launch-National-Education-Campaign-on-Crib-Safety-For-New-and-Expectant-Parents; *see also* RX-37 (2022 AAP infant sleep recommendations).

[135] *See* https://www.cpsc.gov/Recalls/2021/The-Boppy-Company-Recalls-Over-3-Million-Original-Newborn-Loungers-Boppy-Preferred-Newborn-Loungers-and-Pottery-Barn-Kids-Boppy-Newborn-Loungers-After-8-Infant-Deaths-Suffocation-Risk.

has reviewed the medical consequences to infants that can occur when their breathing is obstructed by the Podster. These years of experience and expertise regarding inclined sleep and other pillow products show that using the Podster unsupervised or for sleep, which is foreseeable, can lead to dangerous and fatal outcomes.

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 or misuse of a consumer product is relevant to the question whether the product is defective. Indeed, the Commission may pursue an action under Section 15 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, for bedsharing, and in other foreseeable manners that will put their infant occupants at risk of death.

Based on the foregoing, the Podsters provide no utility; are not necessary; and pose a hidden, serious risk to a vulnerable population. Moreover, the risk of serious injury and death 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 Podsters renders the products defective.

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

The defective Podsters present a substantial product hazard within the meaning of Section 15(a)(2) of the CPSA because of the pattern of defect, the number of defective Podsters in

commerce, and the severity of the risk posed. Under Section 15(a)(2), a substantial product hazard 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.

The factors listed in 15(a)(2) are disjunctive: <u>any one</u> 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.

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 Podsters, their foreseeable operation and use, and the risk of injury posed by the Podsters.

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 compressible, 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 in a risk of injury—specifically, death through suffocation/asphyxiation—to the uniquely vulnerable infant population. This pattern of defect is present in all 180,000 Podsters.[136]

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, for bedsharing,

[136] CCX-1 (Expert Testimony of Erin Mannen, Ph.D.) at 13 n.5.

on elevated surfaces, and within 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. Further, and as detailed above, the risk of injury posed by the Podster renders the product defective after considering the factors listed in 16 C.F.R. § 1115.4.

Thus, the pattern of defect here, which are present on all Podsters and arise from the defects in the physical design of the product, the operation and use of the product, and the risk of injury posed by the product, create a substantial risk of injury to the public, and therefore present a substantial product 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. *See* 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 or death to infants. It is beyond dispute that the injury that can result from the Podsters—death through suffocation/asphyxiation—is as serious as an injury can be. Accordingly, the sale of 180,000 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 basis for establishing a substantial product hazard determination.

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 produced evidence that 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 and while unsupervised, just feet away from their caregivers/parents.

Because of this severe risk to infants, the Podster's defects in this matter create a substantial risk of injury to the public and, therefore, presents a substantial product hazard. The law does not require 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.

In combination with the Podsters' defects, evidence shows that the pattern of defect, the number of products, and the severity of the risk associated with the Podsters support a finding that the Podsters present a substantial risk of injury to the public. As such, Complaint Counsel has proven, 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.

IV. ACTUAL INJURIES OR DEATHS ARE NOT NECESSARY TO DEMONSTRATE A SUBSTANTIAL PRODUCT HAZARD

Numerous reports of incidents and injuries *are not required* for a showing of a substantial product hazard. Leachco's assertion to the contrary is simply wrong. Complaint Counsel does not need to show that a certain number of injuries occurred, or even that a certain percentage or ratio of injuries to products in commerce exists, 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, at *6, *14 (CPSC July 17, 1991) (a case with no

product-specific injuries, noting "[w]ith 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 [S]ection 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 in that matter). Thus, while Leachco tries to minimize the number of incidents in this matter,[137] a substantial product hazard can be established even with no incidents at all—the law does not require a "body count." *See Forester v. CPSC*, 559 F.2d 774, 788-89 (D.C. Cir. 1977) (noting that in case involving the Federal Hazardous Substances Act (FHSA), an analogous statute to the CPSA also enforced by the Commission, that there was no requirement "to develop a precise 'body count' of actual injuries . . . ."). Nevertheless, and despite Leachco's incorrect interpretation, there have been deadly consequences here—specifically, three infants have died after being placed for sleep in the Podsters, and those deaths underscore the dangerous nature of the product.

V. RESPONDENT'S WITNESSES LACKED CREDIBILITY

Neither of the two witnesses who testified on behalf of Leachco during the hearing provided credible evidence disputing Complaint Counsel's case.

Ms. Peggy Shibata was not a credible expert witness and her testimony should be discounted. First, Ms. Shibata admitted she had never inspected an actual physical sample Podster prior to being on the stand at the hearing.[138] *See, e.g. Huffman v. Electrolux Home Products, Inc.*, 129 F.Supp.3d 529, 537-39 (N.D.Ohio 2015) (finding expert witness unqualified

[137] August 10, 2023 Hearing Transcript, 62:19-63:10 (arguing there is virtually no risk associated with the Podster).
[138] *Id.* at 25:1-3, 28:1-4.

to offer opinion on washing machine in part due to lack of relevant qualifications and failure to inspect product samples for design defects). This failure to inspect a sample fatally undermines Ms. Shibata's credibility. Further, at the hearing, she conceded this was not the first occasion in which her expertise was questioned based on her failure to conduct an actual physical inspection while instead relying only on photographs.[139] Second, Ms. Shibata's opinion purported to say that the Podster was necessary because otherwise consumers would resort to less safe products. But under cross examination, she admitted that there were several CPSC approved products that would be an alternative to a Podster.[140] These alternatives are all safer sleep alternatives compared to the Podster. Third, Ms. Shibata conceded during cross that she conducted no affirmative tests, including no live infant testing, seeking to confirm or deny that the Podster presented a suffocation risk.[141] In contrast, and as detailed above and in her testimony, Dr. Mannen conducted numerous tests on the Podster that demonstrated the defects in the Podster. Thus, Ms. Shibata's opinions were cursory, limited to critiques of Complaint Counsel's experts, and did not constitute affirmative evidence of safety. Finally, Ms. Shibata relied on the Schlaud study, a source that she claimed provided support for the view that discounted the relationship between firmness and suffocation risk. But during cross examination, she made an unqualified admission that the source actually stands for the proposition that the presence of pillows *increased the risk of suffocation fourfold*.[142] In sum, for the reasons detailed above, the Court should find Ms. Shibata's testimony to be without evidentiary value, and place no weight upon it.

[139] *Id.* at 25:7-16; 27:6-28:8.
[140] RX-1 (Expert Testimony of Peggy Shibata, April 28, 2023) at 10; August 10, 2023 Hearing Transcript, 37:9-38:19 (admitting that there are CPSC approved alternatives to the Podster including a crib and bassinet).
[141] August 10, 2023 Hearing Transcript, 41:19-42:14 (Ms. Shibata admitting she performed no tests on the Podster including no airflow testing, firmness testing, no carbon dioxide testing and no testing for suffocation risk).
[142] RX-1 (Expert Testimony of Peggy Shibata, April 28, 2023) at 21-22; August 10, 2023 Hearing Transcript, 40:13-41:15 (discussing Schlaud study); *see also* CCX-60 (Schlaud German Study of SIDS) at 6 (stating that "In our study, use of a pillow in the cot was associated with a fourfold increase in the risk of SIDS.").

Ms. Jamie Leach was also not a credible witness, contradicting her own prior declaration during her live testimony. In particular, Ms. Leach claimed that the Podster was safe, and yet she had no basis for such claims: she never used the Podster for any human infants or conducted any testing for suffocation risk.[143] Instead, she offered her personal and monetarily-motivated opinion. Her claims of safety were further undermined by her admission that she took no action other than read the reports from CPSC regarding the three infant deaths associated with the use of the Podster.[144] For example, Ms. Leach did not convene internal meetings to discuss the incidents, did not consider a recall or hire outside experts to conduct suffocation testing, or otherwise assess the risk of injury or death. Ms. Leach also asserted that the Podster afforded medical benefits for breathing and digestion, but was forced to concede she had no specific medical studies or other expertise to back up that claim.[145] Ms. Leach also conceded that "you can't control where babies choose to go to sleep" which is an acknowledgement that babies will in fact fall asleep in a product that she has marketed and sold for years—a claim that Leachco has argued against throughout the pendency of this matter.[146] Thus, the Court should accord no weight to Ms. Leach's testimony and claims regarding the Podster, in light of the inconsistencies and responses lacking credibility.

VI. RESPONDENT HAS THE FINANCIAL MEANS TO CONDUCT A MANDATORY RECALL, MANDATORY NOTIFICATION OF THE RECALL IS REQUIRED IN ORDER TO ADEQUATELY PROTECT THE PUBLIC AND MANDATORY REFUNDS ARE IN THE PUBLIC INTEREST

After the hearing, on August 25, 2023, Leachco provided four documents that purported to provide certain limited and excerpted tax and income information. This information is not

[143] August 8, 2023 Hearing Transcript, 125:3-17.
[144] *Id.* at 143:15-146:9.
[145] *Id.* at 112:7-113:1.
[146] August 8, 2023 Hearing Transcript, 127:2-7.

relevant because nothing in the CPSA requires the Court to consider a manufacturer or distributor's finances when ruling on whether a product poses a substantial product hazard and issuing a mandatory recall order. *See* 15 U.S.C. § 2064(d). The financial documents provided by Leachco contain numerous discrepancies, including that the documents are "unaudited," that several of the tax forms are not signed and only certain parts of the tax returns were provided while omitting other potentially related portions. However, if the Court does consider Leachco's post-hearing submissions, it should also review the declaration attached as Exhibit B from Complaint Counsel's expert staff economist. In sum, that declaration details [redacted] Accordingly, for the reasons further detailed in the attached Declaration, the Court should enter the Order attached to this brief including the provisions for a mandatory recall without any limitations based on Leachco's finances.

Furthermore, the public and direct consumer notice set forth in Complaint Counsel's Proposed Order attached as Exhibit A are required in order to adequately protect the public, as contemplated by 15 U.S.C. § 2064(c)(1). It also furthers the enumerated purpose of the CPSA which is "to protect the public against unreasonable risks of injury associated with consumer products." 15 U.S.C. § 2051(b)(1). Approximately 180,000 hazardous Podsters remain in the stream of commerce, and notice is required in order to effectuate the successful recall of these products, as well as to ensure that any consumer who purchased or possesses a Podster has been properly informed of the potential dangers and the remedies available to address those hazards. Therefore, the Proposed Order requires Leachco to cease distribution of the Podster and to notify

all distributors and retailers to likewise cease distribution. *See* 15 U.S.C. § 2064(c)(1)(A)-(B). Additionally, it instructs Leachco to post clear and conspicuous public notice of the recall on its website and social media accounts. *See* 15 U.S.C. § 2064(c)(1)(D). Finally, the Proposed Order requires Leachco to provide direct consumer notice of the recall, which the Commission has recognized "is the most effective form of a recall notice." 16 C.F.R. §§ 1115.26(a)(4) (part of Subpart C of 16 C.F.R. § 1115, Guidelines and Requirements for Mandatory Recall Notices). The contents of these notices, attached as drafts to Attachments A-F to the Proposed Order, reflect the content required by Section 15(i) of the CPSA, and its regulations at 16 C.F.R. §§ 1115.23-.29.

Finally, pursuant to 15 U.S.C. § 2064(d)(1), an order requiring Leachco to provide consumers with a refund of the purchase price conditioned on return or proof of destruction is in the public interest. Providing a refund will incentivize consumers to return the product and will prevent future sales of the Podsters on second-hand markets. In light of the ongoing substantial risk of injury or death to children posed by the Podsters, action to promote the removal of these products from the marketplace is needed to remediate the hazards and to ensure the Podsters are no longer a threat to consumers. As the Commission has previously recognized, "a substantial refund . . . is the best and most adequate incentive to encourage consumers to participate in the recall." *Zen Magnet*s, 2017 WL 11672451, at *11 (Dec. 8, 2017).

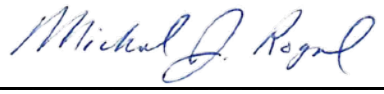
VII. CONCLUSION

Complaint Counsel has proven 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, compressible, 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" and renders the Podster defective. Based on the pattern 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 29th day of September, 2023

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2023, I served Complaint Counsel's Post-Hearing Brief as follows:

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Exhibit A

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

[PROPOSED] INITIAL ORDER

Having considered the arguments and evidence of record in this proceeding, the Court finds:

1. The Leachco Podster ("Subject Product"), manufactured and distributed by Respondent, Leachco, Inc. ("Leachco"), presents a substantial product hazard under Section 15(a)(2) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2064(a)(2);

To remedy Leachco's sale of the Subject Products and in furtherance of the public interest, it is ORDERED that Leachco do the following pursuant to the CPSA, 15 U.S.C. § 2064(c) and (d):

2. Immediately cease distribution of the Subject Products and notify all persons or entities that transport, store, distribute, or otherwise handle any Subject Product, or to which any Subject Product has been transported, sold, distributed, or otherwise handled, to immediately cease distribution of the Subject Products (using the notification attached as Attachment A);

3. Issue notifications of the substantial product hazards presented by the Subject

Products in accordance with 15 U.S.C. § 2064(i)(2) and the Guidelines and Requirements for Mandatory Recall Notices as set forth at 16 C.F.R. §§ 1115.23 - 1115.29, attached as Attachments B and C, as follows:

a. Within ten (10) days of this Order becoming the Final Decision and Order of the Commission pursuant to 16 C.F.R. § 1025.52, the CPSC shall publish the press release (Attachment B) on its website, and Leachco shall simultaneously send a first round of notifications by email, text or other CPSC-staff approved means to all known persons to whom the Subject Products were delivered or sold (Attachment C for consumers; Attachment D for retailers/distributors). Leachco shall send a second round of notifications by email, text or other CPSC-staff approved means (Attachments C, D) approximately two weeks after sending the first round of notifications. If Leachco does not have email addresses or phone numbers for texts for such known persons, Leachco will send the notifications described above by U.S. mail, or other CPSC-staff approved means, consistent with the timeframes noted above;

b. Within ten (10) days of this Order becoming the Final Decision and Order of the Commission pursuant to 16 C.F.R. § 1025.52, Leachco shall:

    i. Create a clear and conspicuous CPSC staff-approved notice of the recall to be placed on Leachco.com, in a form substantially similar to the draft press release

(attached as Attachment B), and publish the notice on Leachco.com simultaneous to the CPSC publishing the press release on its website;

ii. Post the CPSC staff-approved notices attached as Attachment E on its social media platforms (Facebook: https://www.facebook.com/leachco/; Pinterest: @Leachco; Instagram: @Leachco_inc; Twitter/X: @Leachco). Leachco shall issue the social media notices on the same date as the CPSC press releases and first round of notifications in Paragraph 3.a. are disseminated. Leachco shall make the social media post issued on the first day of the recall a "permanent" or "grid" post on each of its accounts. Additionally, Leachco shall post the notice to its social media accounts once every seven (7) calendar days for three (3) weeks after the first announcement is made. All social media notices published by Leachco in connection with this recall shall remain posted with appropriate privacy controls to be visible to the general public;

iii. Digital Advertising. Leachco shall initiate CPSC staff-approved paid social media advertising about the recall from its primary, most-followed, and U.S.-based social media accounts across all social media platforms in which

Leachco maintains an active presence (Facebook, Instagram, Twitter and Pinterest).

- Leachco shall base its social media advertising targeting on the consumer profile it used to market the Podsters. This targeting will include but not be limited to location, interests, economic status, languages and all other demographic targeting options available through social media advertising platforms.
- Leachco shall run the paid social media campaign for the first 30 calendar days after the Press Release is announced with a budget allocation that guarantees at least 80% of Leachco's social media followers will see the recall information at least once.

iv. Leachco shall implement other CPSC staff-approved digital advertising about the recall in the first 30 calendar days after the Press Release is announced to include:

- search engine advertisements (Google, Bing, etc.) for searches involving similar products, key phrases, etc. (*e.g.*, Leachco, Podster, Lounger, Infant Pillow);

- display ads to retarget visitors to retailer websites in the first 30 calendar days after the Press Release is announced; and
- videos announcing the recall and demonstrating how to participate.

v. Maintain the notice on its website for a minimum of 120 days.

vi. Send notice of the substantial product hazard posed by the Subject Products to known second-hand retailers, thrift stores, and online re-sale websites including Facebook Marketplace, Alibaba, Etsy, eBay, Offerup, Alibaba and Craigslist (Attachment F); Leachco shall issue the notice to the second-hand retailers, thrift stores, and online resale websites on the same date the press release and notifications in Paragraph 3.a. are disseminated.

c. Within ten (10) days of this Order becoming the Final Decision and Order of the Commission pursuant to 16 C.F.R. § 1025.52 and prior to the issuance of the press release, the notice on Leachco's website, and the email notifications to consumers, Leachco shall establish the contact information required by 15 U.S.C. § 2064(i)(2)(H)(iii) and 16 C.F.R. § 1115.27(n)(3) to provide information about the remedy to consumers, including a toll-free telephone number staffed by personnel familiar with the recall and open during regular business hours, a dedicated website URL for CPSC staff-approved frequently-

asked questions ("FAQs"), and an email address (together, the "recall response system") for consumers to respond to the recall announcement. The toll-free telephone number and the website shall include CPSC staff-approved information about the hazard posed by the Subject Products and the remedy described in Paragraph 4. below;

i. Leachco shall activate the recall response system referenced in Paragraph 3.c. above prior to the issuance of the press release and shall maintain it for a minimum of ten (10) years.

4. Leachco shall instruct consumers to respond to its email notification directly to Leachco's email address described in Paragraph 3(c) above to arrange for a prepaid mailing package and shipping label to be sent to them to facilitate return of the Subject Products. Upon receipt of the returned Subject Products, Leachco shall refund consumers the purchase price of the products to consumers. No expense shall be incurred by consumers in returning or destroying the Subject Products.

5. Leachco shall immediately quarantine, segregate and mark as recalled all Subject Products in its possession, custody or control, including all Subject Products that are returned from its distribution chain or from consumers. In addition, Leachco shall:

a. Quarantine, retrieve, and destroy the Subject Products possessed by Leachco and returned by consumers;

b. Inform any third-party entities to destroy or return to Leachco any

Subject Products in their inventory; and

c. Submit to Complaint Counsel, in the form of a certificate or declaration of an individual with personal knowledge, proof of destruction of any remaining Subject Products possessed by Leachco and of all returned Subject Products.

d. Prior to the disposal or destruction of the Subject Products in the distribution chain and in inventory (including transfer for disposal or destruction to a third party), Leachco shall notify recalledproductdisposal@cpsc.gov and Complaint Counsel so that CPSC may have the opportunity to witness such disposal, destruction, or transfer of the Subject Products. The notification shall include the items being destroyed, quantity being destroyed, location of destruction, and the planned method of destruction. CPSC may witness or verify such disposal, destruction, or transfer of the Subject Products at CPSC's discretion. In addition, CPSC may request that Leachco verify such destruction through sworn affidavit or other means.

e. The method of destruction employed by Leachco shall comply with all federal, state, and local regulations, and Leachco shall ensure that the Subject Products are destroyed so that they cannot be reused or reenter the stream of commerce.

f. Leachco shall adhere to a plan provided to CPSC for recovery and destruction of the Subject Products (commonly referred to as reverse

logistics) and ensure any involved third-party firms are correctly carrying out the plan. Leachco must immediately contact CPSC if there are any issues with the adherence to the plan, even if those issues arise at the third party. Leachco shall implement the following reverse logistics plan to return product for correction and prevent re-entry of uncorrected Subject Products into commerce:

i. Leachco shall direct retrieval of Subject Products from consumers by mail or contracted pickup.

ii. If Leachco determines or is informed that Subject Products have re-entered commerce after the date of the recall Press Release:

- Leachco shall report that information to the CPSC Office of Compliance and Field Operations immediately.
- Leachco shall reinforce the stop-sale notification and reverse logistics process to ensure they are properly in place.
- Leachco shall change its reverse logistics program to address any deficiencies that allowed the Subject Products to re-enter commerce.

iii. Depending on the circumstances, Leachco and CPSC may re-announce the recall through issuance of another recall Press Release.

6. Leachco shall submit via the electronic Monthly Progress Report system (https://apps.saferproducts.gov), once per month, within 5 business days of the first of each month, starting the first full month after this Order becomes the Final Decision and Order of the Commission pursuant to 16 C.F.R. § 1025.52, and until a closure letter is issued by CPSC staff, Monthly Progress Reports for the Subject Products detailing the implementation of this Order, including, but not limited to, the following:

a. The information referenced in Paragraphs 4(a) through 4(d) above;

b. The number of Subject Products in the possession of manufacturers, distributors, retailers, and consumers;

c. The number of Subject Products possessed by Leachco that were destroyed during the reporting dates, along with proof of destruction in the form of a certificate or declaration of an individual with personal knowledge;

d. The number of incidents, injuries, and deaths reported to Leachco during the reporting dates that are related to the Subject Products;

e. The number of consumers notified about the Subject Products during the reporting dates;

f. The number of consumers who contacted Leachco about the Subject Products during the reporting dates;

g. The number of website hits that Leachco received on its dedicated website for the recall of the Subject Products during the reporting dates;

h. The number of times Leachco posted the recall notice on its social media platforms during the reporting dates; and

i. Whether Leachco located any additional units of the Subject Products for sale on other platforms, including, but not limited to, online re-sale, auction, and wholesale websites.

7. Leachco shall also immediately (within 24 hours) notify CPSC staff of any report of a fatality involving a Subject Product in the United States. Leachco shall further promptly notify CPSC staff of any report of a fatality involving a Subject Product outside of the United States about which Leachco has information.

8. Leachco shall create and maintain a Compliance Program designed to ensure compliance with the CPSA and all other Acts and regulations administered by the CPSC. Leachco shall identify a Safety Officer or Safety Committee responsible for the Firm's compliance. Leachco shall provide CPSC staff with documentation of the program and the specific modifications to its existing Program, if any, to address any material deficiencies, within 90 days after this Order becomes the Final Decision and Order of the Commission pursuant to 16 C.F.R. § 1025.52.

9. Leachco shall Maintain all records of actions taken to comply with the Order for a period of ten (10) years after the service of the Order, and supply such records to Complaint Counsel upon request so that Complaint Counsel can monitor compliance with the Order.

10. This Order is issued under Section 15 of the CPSA, as amended, 15 U.S.C. §

2064. Any violation of this Order is a "Prohibited Act" within the meaning of Section 19(a)(5) of the CPSA, 15 U.S.C. § 2068(a)(5), and may result in civil and/or criminal penalties under Sections 20 and 21 of the CPSA, 15 U.S.C. §§ 2069 and 2070. Further, any violation of this Order also may result in Commission enforcement of the Order, including pursuant to Sections 22 and 27(b) of the CPSA. *See* 15 U.S.C. §§ 2071, 2076(b); 16 C.F.R. § 1115.21(b).

Dated: _____

_____
Hon. Michael G. Young
Administrative Law Judge

Attachment A – Cease Distribution Notice

IMPORTANT RECALL NOTICE – LEACHCO PODSTERS
CEASE DISTRIBUTION NOTICE

[MONTH] [DAY], [YEAR]

Dear [Retailer/Distributor Name]:

Our records indicate that you transported, stored, distributed, or otherwise handled Podsters, which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime (collectively "Podsters"). These Podsters are subject to a mandatory recall by Leachco, Inc. and the U.S. Consumer Product Safety Commission. [INSERT LINK TO CPSC RELEASE]

The recalled Podsters can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Three deaths have been reported when infants were placed on the Podster for sleep.

The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

Approximately 180,000 Podsters have been sold between 2009 and 2022 for prices ranging from $49 - $89.

Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

Please immediately cease distributing the recalled Podsters. If you have recalled Podsters in your inventory, please destroy them immediately or contact us at [INSERT] for instructions on returning the products for refunds.

If you have any questions, contact Leachco via email at [INSERT EMAIL], by calling toll-free [INSERT], or by visiting our "Frequently Asked Questions" dedicated to the topic at [INSERT LINK].

Thank you for your understanding.

Attachment B – Press Release

U.S. Consumer Product Safety Commission – Recall

Release Date: September DAY, 2023
Release Number: 23-DRAFT

Podster Infant Pillow Recalled by Leachco in Court-Ordered Mandatory Recall Due to Suffocation and Asphyxiation Hazards; Three Infant Deaths Reported

Name of Product: Leachco Podster Infant Pillows

Hazard: The recalled Podster infant pillows can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and can also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Remedy: Refund

Consumers should immediately stop using the Podster and contact Leachco for a full refund.

Consumer Contact: Leachco toll-free at [TBD] from [X] a.m. to [X] p.m. ET Monday through Friday, email at [TBD], online at [TBD] and click on [TBD] for more information.

Washington, D.C. -- The U.S. Consumer Product Safety Commission (CPSC) is announcing a mandatory recall of about 180,000 Leachco, Inc. Podsters due to suffocation and asphyxiation hazards to infants. The recalled Podster infant pillows can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of serious injury or death.

CPSC authorized an administrative complaint on February 9, 2022 seeking a mandatory recall of the Podsters after Leachco refused to recall the product. On [DATE] Administrative Law Judge and Presiding Officer, Michael G. Young, determined that the Podsters pose a Substantial Product Hazard under Section 15 of the Consumer Product Safety Act and ordered a mandatory recall.

Three infants have tragically died while being placed on a Podster for sleep. In December 2015, a four-month-old boy died in Alabama when being placed for a nap in a Podster that was in a crib. In January 2018, a 17-day-old girl died in Texas when co-sleeping in a Podster on an adult bed. In October 2021, a three-month-old girl died in Virginia when being placed for a nap in a Podster that was in a playpen.

Consumers should immediately stop using the Podsters and contact Leachco for a full refund and

instructions on how to return the product in a prepaid mailing package.

This mandatory recall involves the Leachco Podster which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime. The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

The recalled Podsters were sold at Walmart and other stores nationwide and online at Leachco.com, Amazon.com and other websites from 2009 through 2022 for between $49 and $89.

The Podsters were manufactured in the United States by Leachco, Inc. of Ada, Oklahoma.

Photos

Recalled Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

About the U.S. CPSC
The U.S. Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risk of injury or death associated with the use of thousands of types of consumer products. Deaths, injuries, and property damage from consumer product-related incidents cost the nation more than $1 trillion annually. CPSC's work to ensure the safety of consumer products has contributed to a decline in the rate of injuries associated with consumer products over the past 50 years.

Federal law prohibits any person from selling products subject to a Commission ordered recall or a voluntary recall undertaken in consultation with the CPSC.

For lifesaving information:
- Visit CPSC.gov.

- Sign up to receive our e-mail alerts.
- Follow us on Facebook, Instagram @USCPSC and Twitter @USCPSC.
- Report a dangerous product or a product-related injury on www.SaferProducts.gov.
- Call CPSC's Hotline at 800-638-2772 (TTY 301-595-7054).
- Contact a media specialist.

Attachment C – Consumer Letter

IMPORTANT RECALL NOTICE – LEACHCO PODSTERS

[MONTH] [DAY], [YEAR]

Dear [Consumer Name]:

Our records indicate that you previously purchased a Podster, which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime (collectively "Podsters"). These Podsters are subject to a mandatory recall by Leachco, Inc. and the U.S. Consumer Product Safety Commission. [INSERT LINK TO CPSC RELEASE]

The recalled Podsters can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Three deaths have been reported when infants were placed on the Podster for sleep.

The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

Approximately 180,000 Podsters have been sold between 2009 and 2022 for prices ranging from $49 - $89.

Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

Please immediately stop using the recalled Podsters. To receive a full refund for your recalled Podster, you can request a pre-paid mailing label and return the product to us, or visit [LINK] for instructions on providing proof of destruction or disposal.

If you have any questions, contact Leachco via email at [INSERT EMAIL], by calling toll-free [INSERT], or by visiting our "Frequently Asked Questions" dedicated to the topic at [INSERT LINK].

Thank you for your understanding.

Attachment D – Retailer Letter

IMPORTANT RECALL NOTICE – LEACHCO PODSTERS

[MONTH] [DAY], [YEAR]

Dear [Retailer/Distributor Name]:

Our records indicate that you sold or distributed in commerce Podsters, which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime (collectively "Podsters"). These Podsters are subject to a mandatory recall by Leachco, Inc. and the U.S. Consumer Product Safety Commission. [INSERT LINK TO CPSC RELEASE]

The recalled Podsters can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Three deaths have been reported when infants were placed on the Podster for sleep.

The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

Approximately 180,000 Podsters have been sold between 2009 and 2022 for prices ranging from $49 - $89.

Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

Please immediately cease distributing the recalled Podsters. If you have recalled Podsters in your inventory, please destroy them immediately or contact us at [INSERT] for instructions on returning the products for refunds.

Additionally, we request that you send the attached CPSC press release and letter to all known consumers who have purchased the Podster [Attachments B and C]. Please send these notices to all known consumers immediately and send a second round of notices approximately two weeks after sending the first round.

If you have any questions, contact Leachco via email at [INSERT EMAIL], by calling toll-free [INSERT], or by visiting our "Frequently Asked Questions" dedicated to the topic at [INSERT LINK].

Thank you for your understanding.

Attachment E – Social Media

Facebook: Mandatory #RECALL Leachco Podsters models Podster, Podster Plush, Bummzie, and Podster Playtime due to suffocation and asphyxiation hazards. Three infants died when placed for sleep on a Podster. Stop using the recalled Podsters immediately. Get a full refund. Contact Leachco at [INSERT] or [LINK]. Full recall notice: [LINK to press release].

X (formerly Twitter): Mandatory #RECALL @Leachco models Podster, Podster Plush, Bummzie, and Podster Playtime due to suffocation and asphyxiation hazards. Three infants died when placed for sleep on a Podster. Stop using immediately. Get full refund. Contact [LINK] [LINK to press release].

Instagram: Mandatory #RECALL @Leachco models Podster, Podster Plush, Bummzie, and Podster Playtime due to suffocation and asphyxiation hazards. Three infants died when placed for sleep on a Podster. Stop using immediately. Get full refund. Contact Leachco at [LINK] [LINK to press release].

Pinterest: Mandatory #RECALL @Leachco models Podster, Podster Plush, Bummzie, and Podster Playtime due to suffocation and asphyxiation hazards. Three infants died when placed for sleep on a Podster. Stop using immediately. Get full refund. Contact Leachco at [LINK] [LINK to press release].

Attachment F – Second-Hand Notice

IMPORTANT RECALL NOTICE – LEACHCO PODSTERS

[MONTH] [DAY], [YEAR]

Dear [Second-Hand Seller Name]:

Our records indicate that you may have active listings for or consumers may have previously sold Podsters, which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime (collectively "Podsters"), on your platform. These Podsters are subject to a mandatory recall by Leachco, Inc. and the U.S. Consumer Product Safety Commission. [INSERT LINK TO CPSC RELEASE]

The recalled Podsters can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Three deaths have been reported when infants were placed on the Podster for sleep.

The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

Approximately 180,000 Podsters have been sold between 2009 and 2022 for prices ranging from $49 - $89.

Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

Please immediately remove any listings for the Podsters and cease any sales. If you have recalled Podsters in your inventory, please destroy them immediately or contact us at [INSERT] for instructions on returning the products for refunds.

Additionally, we request that you send the attached CPSC press release and letter to all known consumers who have purchased the Podster [Attachments B and C]. Please send these notices to

all known consumers immediately and send a second round of notices approximately two weeks after sending the first round.

If you have any questions, contact Leachco via email at [INSERT EMAIL], by calling toll-free [INSERT], or by visiting our "Frequently Asked Questions" dedicated to the topic at [INSERT LINK].

Thank you for your understanding.

Exhibit B (Submitted *in camera)*