

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 MEMORANDUM IN SUPPORT OF
MOTION FOR PARTIAL SUMMARY DECISION
AND STATEMENT OF UNDISPUTED MATERIAL FACTS**

Pursuant to 16 C.F.R. §§ 1025.23 and 1025.25, Complaint Counsel respectfully submits this memorandum in support of its motion for partial summary decision. As explained in further detail below, summary decision should be entered on the following issues: (1) it is foreseeable that consumers will use the Leachco, Inc. Podster¹ for infant sleep; (2) it is foreseeable that consumers will use the Podster without constant supervision; and, (3) as a result, the Podster presents a substantial risk of injury.

I. INTRODUCTION

Complaint Counsel brought this administrative action against Respondent Leachco, Inc. (“Leachco”), alleging that Leachco’s Podster—an infant lounging pillow—poses a substantial product hazard under Section 15(a)(2) of the Consumer Product Safety Act.² Specifically, Complaint Counsel alleges that the soft, pillowlike Podster poses a deadly suffocation hazard for

¹ For the purposes of this Memorandum, “Podster” refers to the Podster line of products manufactured by Leachco, including the Podster, Podster Plush, Bummzie, and Podster Playtime. *See* Dkt. 1, Compl. ¶¶ 8–10.

² *Id.* at ¶¶ 48–52.

infants—a uniquely vulnerable population—if they are left unattended or for sleep in the product.³

In the 16 months since this lawsuit was filed, the parties have engaged in extensive fact discovery, including written discovery and numerous depositions. Complaint Counsel also has presented the testimony of three expert witnesses at the forefront of their fields. Dr. Erin Mannen, a professor and researcher in the field of mechanical and biomechanical engineering, has presented testimony about the physical design defects of the Podster. Dr. Umakanth Katwa, a lecturer at Harvard Medical School and an attending physician in the Division of Pulmonary Medicine at Boston Children’s Hospital, has testified about how those design defects can lead to suffocation, asphyxia, and, ultimately, death in infants. And Celestine Kish, an engineering psychologist with over three decades of experience in her field, offered testimony explaining that it is foreseeable that caregivers will use the Podster for infant sleep and will use the Podster without constantly supervising the infant placed on the product. [REDACTED]

[REDACTED]

[REDACTED]

This expert testimony and the additional factual information gathered during the course of discovery further bolster Complaint Counsel’s claim that the Podster is potentially deadly to its infant occupants and poses a substantial product hazard. Despite the strength of its substantial product hazard case, Complaint Counsel has elected not to seek summary decision with respect to the entire matter, as Complaint Counsel recognizes there are certain factual matters Leachco still contests relating to whether the product is defective, despite the weight of evidence against it.

³ *Id.* at ¶¶ 20–37.

Complaint Counsel instead seeks summary decision on three relatively narrow issues that will serve to focus and streamline the hearing scheduled to begin on August 7, 2023.

Specifically, Complaint Counsel asks the Presiding Officer to enter an order establishing: (1) it is foreseeable that consumers will use the Podster for infant sleep; (2) it is foreseeable that consumers will use the Podster without constant supervision; and, (3) as a result, the Podster presents a substantial risk of injury. These issues cannot validly be contested by Leachco and thus are ripe for summary decision.

II. STATEMENT OF UNDISPUTED MATERIAL FACTS

A. Respondent Leachco, Inc.

[REDACTED]

Leachco manufactures, distributes, and offers for sale more than 90 products, including pillows for infants, children, and nursing caregivers. Leachco markets and sells its products through its website www.leachco.com, as well as through retailers such as Amazon.com, Walmart, and others.⁵

[REDACTED]

[REDACTED]

[REDACTED] Leachco has approximately 50 employees and is located in Ada, Oklahoma.¹⁰

⁴ Jamie Leach Deposition, March 1, 2023 at 15:2-4 (Exhibit 1). All Exhibits referenced in this Memorandum are Exhibits to the Declaration of Michael J. Rogal in Support of Complaint Counsel's Motion for Partial Summary Decision that accompanies this filing.

⁵ Complaint, Dkt. No. 1, ¶ 12; Answer, Dkt. No. 2, ¶ 11; Alex Leach Deposition, February 15, 2023 at 82:3-16 (Exhibit 2).

⁶ Jamie Leach Deposition, March 1, 2023 at 16:1-4, 17:18-20 (Exhibit 1); Leachco Organizational Chart, May 11, 2022, Leachco-CPSC-000002 (Exhibit 3).

⁷ Jamie Leach Deposition, March 1, 2023 at 12:6-13, 22:17-23:15 (Exhibit 1).

⁸ *Id.* at 28:4-20 (Exhibit 1).

⁹ Clyde Leach Deposition, February 28, 2023 at 33:4-8 (Exhibit 4); Leachco Organizational Chart, May 11, 2022, Leachco-CPSC-000002 (Exhibit 3).

¹⁰ Leachco's Responses to CPSC's First Set of Interrogatories, May 13, 2022, at 2 (response to Interrogatory No. 3)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. The Subject Products

The Subject Products are various models of the “Podster” infant lounging pillows, including the Podster, Podster Plush, Bummzie, and Podster Playtime models.¹⁵ The Podsters are manufactured in Leachco’s facilities in Ada, Oklahoma.¹⁶ The Podsters are distributed and offered for sale to consumers for their personal use.¹⁷ Since 2009, Leachco has manufactured and distributed approximately 180,000 Podsters.¹⁸

Leachco sold the Podster for a retail price ranging from \$49 and \$89.¹⁹ [REDACTED]

[REDACTED]

[REDACTED] The Podster’s packaging and Leachco’s website markets the Podster as a “Sling-Style Infant Lounger” that “provides a warm and cozy caress for infants” and “provides upper body elevation which can help aid in digestion and breathing,” as well as featuring “deeply contoured

(Exhibit 5); Clyde Leach Deposition, February 28, 2023 at 62:14-17 (Exhibit 4).

¹¹ Clyde Leach Deposition, February 28, 2023 at 88:21-89:8 (Exhibit 4).

¹² *Id.* at 88:21-89:4 (Exhibit 4).

¹³ Web Data Collection, February 7, 2023 for www.leachco.com/collections/leachco-catalog (Exhibit 6); Alex Leach Deposition, February 15, 2023 at 83:18-21 (Exhibit 2); Clyde Leach Deposition, February 28, 2023 at 99:10-104:7 (Exhibit 4).

¹⁴ Alex Leach Deposition, February 15, 2023 at 83:8-13 (Exhibit 2); Clyde Leach Deposition, February 28, 2023 at 104:7-105:7 (Exhibit 4).

¹⁵ Complaint, Dkt. No. 1, ¶ 7, 9; Answer, Dkt. No. 2, ¶ 7, 9.

¹⁶ Complaint, Dkt. No. 1, ¶ 8; Answer, Dkt. No. 2, ¶ 8.

¹⁷ Complaint, Dkt. No. 1, ¶ 7; Answer, Dkt. No. 2, ¶ 7.

¹⁸ Complaint, Dkt. No. 1, ¶ 10; Answer, Dkt. No. 2, ¶ 10.

¹⁹ Complaint, Dkt. No. 1, ¶ 11; Answer Dkt. No. 2, ¶ 10.

²⁰ Jamie Leach Deposition, March 1, 2023 at 86:16-22 (Exhibit 1).

sides” that hold the infant.²¹ Leachco’s marketing materials claim that an adult can multitask hands-free while an infant is in the Podster—meaning a caregiver may engage in activities like “prepare a meal, pay bills, check email, give a hand to siblings and many other daily tasks.”²²

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

C. Consumers’ 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.²⁵ [REDACTED]

[REDACTED]

[REDACTED]

Despite Leachco’s warnings and instructions, caregivers use the Podster for infant sleep.²⁷ There are several reasons why this is not a matter of material dispute. First, parents and caregivers are motivated to have infants under their care fall and stay asleep for extended periods of time. [REDACTED]

²¹ *Id.* at 157:4-158:10; (Exhibit 1); Leachco’s Objections and Responses to CPSC’s Second Set of Requests for Admission, November 30, 2022, Response to RFA No. 2 at 1-2 (Exhibit 7).

²² Expert Testimony of Celestine Kish, May 2, 2023 at 63 (Exhibit 10) (quoting Leachco’s website).

²³ Jamie Leach Deposition, March 1, 2023 at 87:14-20 (Exhibit 1); Tonya Barrett Deposition, February 1, 2023 at 77:11-21 (Exhibit 8).

²⁴ Jamie Leach Deposition, March 1, 2023 at 34:16-35:8 (Exhibit 1); Tonya Barrett Deposition, February 1, 2023 at 36:15-37:14, 76:21-77:13 (Exhibit 8); Clyde Leach Deposition, February 28, 2023 at 116:2-121:6 (Exhibit 4); Clyde Leach Deposition Exhibit No. 3 (Podster Test Reports, LC-88-167) (Exhibit 9).

²⁵ Complaint Dkt. No. 1, ¶ 14-15; Answer Dkt. No. 2, ¶¶ 13-14.

²⁶ Expert Testimony of Celestine Kish, May 2, 2023 at 57 (Exhibit 10).

²⁷ Complaint Dkt. No. 1, ¶ 23; Answer Dkt. No. 2, ¶ 22.

[REDACTED]

Second, the Podster is used for sleep because many parents and caregivers are influenced by social media and other images showing infants sleeping on the Podster. [REDACTED]

[REDACTED]

²⁸ Expert Testimony of Celestine Kish, May 2, 2023 at 57 (Exhibit 10).

²⁹ *Id.* at 70-71 (Exhibit 10); Mabry Ballard Deposition, January 31, 2023 at 17:7–18:8, 180:15–19 (Exhibit 14); Tonya Barrett Deposition, February 1, 2023 at 27:20–28:12, 29:8–30:9 (Exhibit 8).

³⁰ 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) (Exhibit 11).

³¹ Alex Leach Deposition, February 15, 2023 at 141:8-16 (Exhibit 2).

³² Leah Barnes Deposition, February 16, 2023 at 118:18-120:10, 132:19-134:8 (Exhibit 16) [REDACTED]

³³ Expert Testimony of Celestine Kish, May 2, 2023 at 34-39 (Exhibit 10).

³⁴ *Id.* at 39-53 (Exhibit 10); Leachco’s Second Supplemental Response to CPSC RFA Nos. 3, 4, & 5, March 13, 2023 at 5 (second supplemental response to RFA No. 5) (Exhibit 11) (admitting that Leachco “had knowledge that there were reviews on Amazon.com that referenced infants sleeping on Podsters”).

[REDACTED]

[REDACTED]

[REDACTED]

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. [REDACTED]

[REDACTED]

[REDACTED]

Fifth, parents and caregivers may use the Podster for bedsharing or co-sleeping. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Finally, tragically, the three reported incidents of infant deaths associated with use of the Podster confirm that caregivers will use the Podster for sleep. In each of the three fatal incidents, the infant was placed in the Podster for sleep before suffocating.³⁹

The testimony of Leachco's expert, Ms. Shibata, does not materially contradict this expert testimony and the research cited by Ms. Kish.⁴⁰

D. Consumers' 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

³⁵ Expert Testimony of Celestine Kish, May 2, 2023 at 39-53 (Exhibit 10).

³⁶ *Id.* at 59 (Exhibit 10).

³⁷ *Id.* at 2 (Exhibit 10).

³⁸ *Id.* at 60-61 (Exhibit 10).

³⁹ *Id.* at 67-70 (Exhibit 10); Expert Testimony of Umakanth Katwa, April 28, 2023 at 26-29 (Exhibit 13); *see also* Leachco's Objections and Responses to CPSC First Set of Requests for Admission, November 30, 2022 at 3-4 (Response to RFA No. 6) (Exhibit 7).

⁴⁰ *See* Expert Testimony of Peggy Shibata, April 28, 2023 at 10 (Exhibit 12).

activities like “prepare a meal, pay bills, check email, give a hand to siblings and many other daily tasks.”⁴¹ [REDACTED]

[REDACTED] The testimony of Leachco’s expert, Ms. Shibata, does not materially contradict this expert testimony and the research cited by Ms. Kish.⁴⁷

E. Infants Placed in a Podster May Suffer Severe Injury or Death

The Podster presents several scenarios that can cause severe injury or death to an infant.

⁴¹ Expert Testimony of Celestine Kish, May 2, 2023 at 63 (Exhibit 10) (quoting Leachco’s website).

⁴² *Id.* at 62-63 (Exhibit 10).

⁴³ *Id.* at 62 (Exhibit 10).

⁴⁴ *Id.*

⁴⁵ *Id.* at 63-64 (Exhibit 10). Nothing in Peggy Shibata’s expert testimony contradicts Ms. Kish’s expert testimony regarding the impossibility of constant supervision while using the Podster.

⁴⁶ *Id.* at 63 (Exhibit 10). [REDACTED]

[REDACTED] Expert Testimony of Peggy Shibata, April 28, 2023 at 14 (Exhibit 12).

⁴⁷ *See id.* at 10 (Exhibit 12) [REDACTED]

⁴⁸ Expert Testimony of Umakanth Katwa, April 28, 2023 at 10 (Exhibit 13).

⁵⁷ *Id.* at 19 (Exhibit 13).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The testimony of Leachco’s expert, Ms. Shibata, does not materially contradict this expert testimony and the research cited by Dr. Katwa.⁶²

III. LEGAL STANDARD FOR SUMMARY DECISION

Under the Commission’s Rules of Practice for Adjudicative Proceedings, any party may file a motion, with a supporting memorandum, for a Summary Decision and Order in its favor upon all or any of the issues in controversy. 16 C.F.R. § 1025.25(a). Such a motion “shall be granted if the pleadings and any depositions, answers to interrogatories, admissions, or affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to a Summary Decision and Order as a matter of law.” 16 C.F.R. § 1025.25(c).

Section 1025.25’s Summary Decision standard is similar to Rule 56(a) of the Federal Rules of Civil Procedure, which states in relevant part:

(a) Motion for Summary Judgment or Partial Summary Judgment. A party may move for summary judgment, identifying each claim or defense—or the part

⁵⁸ *Id.* at 21 (Exhibit 13).

⁵⁹ *Id.* at 14 (Exhibit 13).

⁶⁰ *Id.* at 25-26 (Exhibit 13).

⁶¹ *Id.* at 26-29 (Exhibit 13). Nothing in Leachco’s expert testimony contradicts Dr. Katwa’s findings regarding the risk or serious injury and/or death due to suffocation risk. Expert Testimony of Peggy Shibata, April 28, 2023 (Exhibit 12).

⁶² See Expert Testimony of Peggy Shibata, April 28, 2023 at 5-7 (Exhibit 12).

of each claim or defense—on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.⁶³

In interpreting the Rule 56 standard, the Supreme Court of the United States has held that the appropriate inquiry at summary judgment is not whether issues of fact exist, but whether any issue of “material fact” exists: “Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Moreover, “[w]hen the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). “The mere existence of a scintilla of evidence” is insufficient to defeat summary judgment. *Anderson*, 477 U.S. at 252. The Supreme Court also has noted that summary judgment “is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed ‘to secure the just, speedy and inexpensive determination of every action.’” *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1).

Under Section 1025.25(a), a court may grant summary decision as to “any of the issues in controversy,” similarly to how Federal Rule of Civil Procedure 56(a) permits a federal court to grant summary judgment on “part of” a claim or defense. *See* Fed. R. Civ. P. 56, Advisory Committee Notes, 2010 Amendment (“The first sentence is added to make clear at the beginning that summary judgment may be requested not only as to an entire case but also as to a claim,

⁶³ Although the Federal Rules of Civil Procedure do not govern here, many administrative proceedings have looked to case law applying analogous Federal Rules for guidance in construing administrative rules of practice. *See, e.g., In re Healthway Shopping Network*, Exch. Act Rel. No. 89374, 2020 WL 4207666, at *2 (Jul. 22, 2020) (SEC guided by precedent applying Federal Rules in interpreting its own administrative rules of practice).

defense, or part of a claim or defense. The subdivision caption adopts the common phrase ‘partial summary judgment’ to describe disposition of less than the whole action, whether or not the order grants all the relief requested by the motion.”); *see also United States v. Mirama Enterprises*, 185 F. Supp. 1148, 1164 (S.D. Cal. 2002) (granting motion for partial summary judgment as to liability for civil penalty matter under CPSA), *aff’d*, 387 F.3d 983, 989 (9th Cir. 2004).

Because there is no dispute as to the material facts demonstrating that (1) it is foreseeable that consumers will use the Podster for infant sleep; (2) it is foreseeable that consumers will use the Podster without constant supervision; and (3) as a result, the Podster presents a substantial risk of injury, summary decision for Complaint Counsel is appropriate as to those issues.

IV. ARGUMENT

A. It Is Foreseeable that Caregivers Will Use the Podster for Infant Sleep and Without Constant Supervision

Summary decision should be granted and an order should be issued establishing that (1) it is foreseeable that consumers will use the Podster for infant sleep and (2) it is foreseeable that consumers will use the Podster without constant supervision. There is no genuine issue of material fact as to either of those subjects.

1. Foreseeable Uses of the Podster Are Relevant to the Question Whether the Podster Is Defective

Entering summary decision as to the foreseeable uses of the Podster will help inform the Presiding Officer’s later determination of whether the Podsters are defective.

The Commission’s definition of “defect” under 16 C.F.R. § 1115.4 contemplates that “[r]easonably foreseeable consumer use or misuse” is relevant to the consideration of whether a consumer product has a defect that can lead to a substantial product hazard. 16 C.F.R. §

1115.4(d). Section 1115.4 further states that “the role of consumer misuse of the product and the foreseeability of such misuse” is relevant to assessing whether a defect exists. 16 C.F.R. § 1115.4(e). “[T]he intended or reasonably foreseeable use or misuse of the product” also is a factor in evaluating the severity of the risk posed by the defect and, therefore, whether the defect creates a substantial risk of injury to the public. 16 C.F.R. § 1115.12(g)(1)(iii).

The district court in *Zen Magnets v. CPSC* affirmed the relevance of foreseeable use and misuse in evaluating whether a product poses a substantial product hazard. 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). There, the respondent contended that the Commission wrongly examined the foreseeable misuse of the product at issue in determining that it was defective. *Id.* But the court disagreed with the respondent, pointed to Section 1115.4’s references to foreseeable use and misuse, and held that “the Commission was entitled to assess the reasonably foreseeable misuse of the magnets in determining the existence of a defect.” *Id.*; *see also Southland Mower Co. v. CPSC*, 619 F.2d 499, 513–14 (5th Cir. 1980) (“Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risk.” (citing *Aqua Slide ‘N’ Dive Corp. v. CPSC*, 569 F.2d 831, 841 (5th Cir. 1978) and legislative history)).

Here, it cannot be disputed that it is foreseeable that caregivers will permit infants to sleep in the Podster and will leave infants in the Podster without constant supervision. Both circumstances increase the risk that an infant will suffocate or suffer from asphyxia due to the Podster, and so both of these foreseeable circumstances contribute to the substantial product hazard posed by the Podster.

2. It Is Foreseeable that Consumers Will Use the Podster for Infant Sleep

It is foreseeable that caregivers will permit infants to sleep in the Podster, and there is no material dispute regarding that issue. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁶⁴ Expert Testimony of Celestine Kish, May 2, 2023 at 57–60 (Exhibit 10); *see also* Expert Testimony of Umakanth Katwa, April 28, 2023 at 26–29 (Exhibit 13).

⁶⁵ Expert Testimony of Celestine Kish, May 2, 2023 at 58 (Exhibit 10); *see also* Expert Testimony of Umakanth Katwa, April 28, 2023 at 14 (Exhibit 13).

⁶⁶ Expert Testimony of Celestine Kish, May 2, 2023 at 58 (Exhibit 10).

⁶⁷ *Id.* at 58 (Exhibit 10).

⁶⁸ *Id.* at 39–53, 57 (Exhibit 10).

[REDACTED]

[REDACTED]

[REDACTED]

Even Leachco itself admitted that consumers have used the Podster for infant sleep. In response to a Request for Admission in this matter, Leachco averred: “Leachco admits consumers allowed infants to sleep on Podsters.”⁷⁶ Leachco also admitted that, before Complaint Counsel initiated this administrative action, “Leachco had knowledge that some consumers had placed some infants on some Podsters and some infants subsequently fell asleep while on the product.”⁷⁷ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Leachco has not presented any evidence that parents and caregivers will not permit infants to sleep in Podsters. Summary decision should be granted on this ground.

3. It Is Foreseeable that Consumers Will Use the Podster Without Constant Supervision

It also is foreseeable that caregivers will not constantly supervise infants while the infants

⁷⁵ *Id.*

⁷⁶ 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) (Exhibit 11).

⁷⁷ *Id.*; see also Alex Leach Deposition, February 15, 2023 at 141:8-16 (Exhibit 2).

⁷⁸ Leah Barnes Deposition, February 16, 2023 at 118:18-120:10, 132:19-134:8 (Exhibit 16) [REDACTED]

[REDACTED]

⁷⁹ Leachco’s Second Supplemental Response to CPSC Request for Admission Nos. 3, 4, & 5, March 13, 2023 at 3-4 (second supplemental response to RFA No. 4) (admitting that “Leachco had knowledge that at least one Retailer included the Podster in what appears to be a category or style called ‘Sleep Positioners’”) and at 4-5 (admitting that “Leachco had knowledge that there were reviews on Amazon.com that referenced infants sleeping on Podsters.”) (Exhibit 11).

⁸² *Id.* at 62 (Exhibit 10).

[REDACTED]

Leachco’s own marketing promotes multitasking while using the Podster, which is at odds with any assertion that constant supervision is required for safe use of the product. The multitasking Leachco promotes in its marketing (“prepare a meal, pay bills, check email, give a hand to siblings and many other daily tasks”) makes it all the more foreseeable that parents will not constantly supervise an infant in the Podster. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Therefore, it is foreseeable that caregivers would not be able to constantly supervise an infant in the Podster if they engage in the very multitasking that Leachco promotes.

In light of the foregoing, summary decision is appropriate here. It is beyond dispute that caregivers will not constantly supervise infants while in the Podster and nothing in the testimony of Leachco’s expert raises a genuine issue of material fact on this point.

4. The Podster’s Warnings Do Not Undermine the Foreseeability of Its Uses

Leachco does not, and cannot, viably contest that caregivers may use the Podster for sleep or leave an infant unattended in the product. [REDACTED]

[REDACTED]

[REDACTED]

⁸³ Expert Testimony of Umakanth Katwa, April 28, 2023 at 4 (Exhibit 13).

⁸⁴ Expert Testimony of Celestine Kish, May 2, 2023 at 64 (Exhibit 10).

⁸⁵ *Id.*

⁸⁶ Expert Testimony of Peggy Shibata, April 28, 2023 at 3-4, 14 (Exhibit 12).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As an initial matter, these arguments go to the larger defect analysis, not the question whether it is foreseeable that caregivers will use the Podster for infant sleep or unsupervised. That question cannot reasonably be contested, nor does Ms. Shibata squarely address the question. It is in fact foreseeable that the Podster will be used for infant sleep and caregivers will permit infants to remain in the product without supervision.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Complaint Counsel acknowledges that the Podsters bear warnings regarding not using the product for infant sleep or while unsupervised (*see* Compl., Dkt. 1 at ¶ 15),⁹¹ but those warnings are insufficient to mitigate the hazard posed by foreseeable uses of the product. [REDACTED]

⁸⁷ *Id.* at 10 (Exhibit 12).

⁸⁸ *Id.* (Exhibit 12).

⁸⁹ *Id.* at 9 (Exhibit 12).

⁹⁰ Expert Testimony of Celestine Kish, May 2, 2023 at 1-2, 55-56 (Exhibit 10).

⁹¹ Dkt. 1, Compl. at ¶ 15.

⁹² Mabry Ballard Deposition, January 31, 2023 at 180:8–19 (Exhibit 14).
⁹³ Expert Testimony of Celestine Kish, May 2, 2023 at 10 (Exhibit 10).
⁹⁴ *Id.* at 2 (Exhibit 10).
⁹⁵ Expert Testimony of Umakanth Katwa, April 28, 2023 at 28–29 (Exhibit 13).
⁹⁶ Expert Testimony of Celestine Kish, May 2, 2023 at 7–56 (Exhibit 10).

[REDACTED]

[REDACTED]

In sum, Leachco has not raised a material dispute regarding whether it is foreseeable that caregivers will use the Podster for infant sleep or unsupervised. [REDACTED]

[REDACTED]

B. The Podster Poses a Substantial Risk of Injury (SRI)

Under the CPSA, the Commission may order a firm to provide notice to the public and take remedial action if the Commission determines that a product “presents a substantial product hazard.” 15 U.S.C. § 2064(c) and (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); *see also In the Matter of Dye and Dye*, Opinion and Order, CPSC Docket No. 88-1, 1989 WL 435534, *13-15 (July 17, 1991) (determining that the subject product created a substantial risk of injury).

Thus, the CPSA sets forth the factors to be considered in determining whether a substantial product hazard exists as a result of a defect which creates a substantial risk of injury:

⁹⁷ *Id.* at 56 (Exhibit 10).

(1) pattern of defect; (2) the number of defective products distributed in commerce; (3) the severity of the risk; or (4) otherwise. 15 U.S.C. § 2064(a)(2); *see* 16 C.F.R. § 1115.12(g)(1).

These factors are disjunctive: any one of the factors standing alone could create a substantial product hazard. 16 C.F.R. § 1115.12(g)(1). This motion for partial summary decision addresses the third factor: the severity of the risk.⁹⁸

Pursuant to the Commission’s regulations, a risk is severe if the injury that might occur is serious and/or likely to occur. 16 C.F.R. § 1115.12(g)(iii). A serious injury is one that results in death, a “grievous bodily injury,” or other significant injury that requires hospitalization; actual medical or surgical treatment; fractures; lacerations requiring stitches; concussions; and injuries to the eye, ear, or internal organs requiring medical treatment or requiring the missing school or work more than one day. 16 C.F.R. § 1115.6(c). A “grievous bodily injury” includes “mutilation, amputation/dismemberment, disfigurement, loss of important bodily functions, debilitating internal disorders, severe burns, severe electrical shocks and injuries likely to require extended hospitalization.” 16 C.F.R. § 1115.12(d).

As to whether an injury is likely to occur, the Commission’s regulations direct the consideration of “the number of injuries reported to have occurred, the intended or reasonably foreseeable use or misuse of the product, and the population group exposed to the product (e.g., children, elderly, [persons with disabilities]).” 16 C.F.R. § 1115.12(g)(1)(iii); *see also In the Matter of Zen Magnets, LLC*, CPSC Docket No. 12-2, Final Decision and Order, October 26, 2017 at 38-42 (finding that the small rare-earth magnets pose a severe risk of injury), *vacated on*

⁹⁸ At the hearing, Complaint Counsel also will be prepared to offer proof on the other SRI prongs: the pattern of defect, the number of defective products distributed in commerce, and otherwise. There is no dispute that “approximately 180,000 Podsters have been manufactured and distributed in U.S. commerce since 2009”: Leachco admits that fact. Dkt 1, Compl. ¶ 10; Dkt. 2, Answer, ¶ 10. And the pattern of design defect is consistent across those Podsters.

other grounds, Zen Magnets v. CPSC, Civil Action No. 17-cv-02645, 2018 WL 2938326, *15 (D. Col. June 12, 2018), *aff'd in part and rev'd in part on other grounds*, 968 F.3d 1156, 1176. (10th Cir. 2020).

Here, the third factor—severity of the risk—is satisfied, and thus the existence of a substantial risk of injury is established. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Neurological injuries are serious injuries, as they could lead to death and/or a grievous bodily injury. 16 C.F.R. § 1115.6(c).

With respect to likelihood of injury, it is undisputed that there were three (3) incidents associated with the use of a Podster that resulted in fatalities to infants, a uniquely vulnerable population. Each of the three incidents also involved foreseeable use of the Podster for sleep, as further discussed *supra*. And in each instance, the Podster was placed on or within a sleep space (a crib, an adult bed, and a playpen) to allow the infant to sleep. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁹⁹ Expert Testimony of Umakanth Katwa, April 28, 2023 at 4–5, 30 (Exhibit 13); *see also infra* at Section II.E.

¹⁰⁰ *Id.* at 22, 25, 30 (Exhibit 13).

¹⁰¹ *Id.* at 24, 26 (Exhibit 13).

¹⁰² *Id.* at 26-27 (Exhibit 13).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

There is no genuine issue of material fact as to the severity of the risk. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thus, because there is no dispute, let alone any genuine issue, of material fact regarding the severity of the risk posed by the Podster, partial summary judgment should be entered as to the substantial risk of injury prong of the substantial product hazard analysis.

¹⁰³ *Id.* at 27 (Exhibit 13).

¹⁰⁴ *Id.* at 28–29 (Exhibit 13).

V. CONCLUSION

In light of the foregoing, Complaint Counsel respectfully requests that the Presiding Officer enter partial summary decision as to the following issues: (1) it is foreseeable that consumers will use the Podster for infant sleep; (2) it is foreseeable that consumers will use the Podster without constant supervision; and (3) as a result, the Podster presents a substantial risk of injury. As explained above, there is no genuine issue as to any material fact with respect to these points, and summary decision is appropriate.

Dated this 9th day of June, 2023

Respectfully submitted,

A handwritten signature in blue ink, reading "Michael J. Rogal", is positioned above a horizontal line.

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