UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

LEACHCO, INC.'S MOTION FOR SUMMARY DECISION AND MEMORANDUM IN SUPPORT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Constitutional Provisions

Regulations

Other Authorities

INTRODUCTION

In this proceeding, the Consumer Product Safety Commission is bringing an arbitrary and capricious action against Respondent Leachco, Inc. Leachco—founded 35 years ago—designs and manufactures safe and helpful products for families. One product is an infant lounger called the Podster. Since 2009, Leachco has sold over 180,000 Podsters. Tragically, three infants have died while in the same location as a Podster. The evidence shows that the three infants were placed in unsafe-sleep environments—among other things, multiple soft items in cribs and co-sleeping circumstances—that unfortunately arise with all manner of nursery-related products. But the Commission does not seek a ban of infant products; nor has it attempted to recall cribs, highchairs, playpens, or other products that are associated with many more infant deaths than the Podster. For whatever reason, the Commission wants to make an example of a small, family business in Ada, Oklahoma.

The Commission alleges one claim under the Consumer Product Safety Act: that the Podster presents a "substantial product hazard," defined as "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2). The claim has no merit whatsoever. Its only chance to succeed is if the Court allows the Commission to radically rewrite the law.

First, the Commission cannot show that the Product is defective under the CPSA. The term "product defect" is not defined by the CPSA. Therefore, its ordinary meaning is used: a product defect is a manufacturing, warning, or design defect. But

the Commission—while it loosely alleges a design defect—claims that the Podster is defective because "it is foreseeable" that consumers "may" misuse it. Under long-standing legal principles, however, foreseeable consumer misuse is a factor that may be used to determine whether a warning is inadequate or whether a reasonable alternative design was possible. (The Commission disclaimed any allegations of inadequate warnings, and it denied that it had any obligation to proffer a reasonable alternative design). But foreseeable misuse is not *itself* a defect.

Second, assuming a defect exists, the Commission has no evidence to show that any defect has "*create[d]* a substantial risk of injury to the public." § 2064(a)(2) (emphasis added). Rather, the risk here resulted from unsafe-sleep environments.

Third, the Commission erroneously contends that "a substantial risk of injury to the public" actually means "a risk of substantial injury." The Commission no doubt feels compelled to alter the statutory language to make this argument due to the facts of the case—only three injuries out of more than 180,000 Podsters. Thus, the Commission asks the Court to pretend that § 2064(a)(2) does not require a showing of substantial *risk*, but merely *any* risk of a substantial *injury*. Aside from requiring an express amendment to the language, the CPSA's definition of "risk of injury" forecloses the Commission's argument. A "risk of injury" is a "a risk of death, personal injury, or serious or frequent illness." § 2052(a)(14). Thus, the "risk of injury"—most obviously, death—is by definition substantial, and the word "substantial" in § 2064(a)(2) must therefore modify the "risk" (of injury) and not "injury." The Commission's argument does not withstand scrutiny.

Fourth, if the Commission's extra-textual interpretations are correct, then the CPSA violates the Major Questions Doctrine, the Nondelegation Doctrine, and Leachco's due process rights.

Finally, to preserve issues for judicial review, Leachco submits that this proceeding is unlawful because: both the Commissioners and the Presiding Officer enjoy unconstitutional removal protections; the President's appointment power is improperly restricted by the CPSA; and this proceeding violates Leachco's rights to due process, an Article III forum, and a jury trial.

Because there are no genuine issues of material fact, and because Leachco is entitled to judgment as a matter of law—because the Commission cannot establish that the Podster presents a "substantial product hazard"—this Court should grant Leachco's motion for summary decision and dismiss the Commission's administrative complaint with prejudice.

BACKGROUND

LEACHCO: JAMIE AND CLYDE'S AMERICAN DREAM

Jamie Leach and her husband Clyde started Leachco out of their home in Ada, Oklahoma 35 years ago.[1] Before starting Leachco, Jamie became a registered nurse, founded, and co-owned a Medicare-certified home-healthcare agency.[2] Jamie later worked as nurse at Valley View Regional Hospital in Ada (1983–1988), where she headed the discharge-planning department and conducted utilization review for in-

[1] Ex. C, Jamie Leach Decl. (Leach Decl.) ¶ 1; Tr., Ex. D, J. Leach Dep., 13:20–14:2.
[2] Ex. C, Leach Decl. ¶ 2; Ex. D, Tr., J. Leach Dep., 12:14–13:7.

patient admission certification and discharge.[3] Clyde worked as a professional pilot and aerial applicator—commonly known as a crop-duster.[4]

A near-accident involving her then-seven-month-old son Alex—now Leachco's COO—inspired Jamie's first design.[5] Baby Alex almost slipped out of a restaurant high-chair due to a missing restraint strap and buckle.[6] Jamie quickly fashioned a temporary fix with her purse strap.[7] Within the next few days, Jamie designed a safety wrap using dental floss, tape, and a kitchen hand towel.[8] The "Wiggle Wrap" was born.[9] Jamie used it often—and other parents began to notice it.[10] Jamie and Clyde believed they were on to something and launched Leachco out of their home on May 30, 1988.[11] They just celebrated their 35th anniversary.

To this day, Jamie still designs Leachco's products—relying on her experiences as a (still-registered) nurse, mother, and grandmother.[12] Along the way, she secured over 40 patents and dozens of trademarks.[13]

Of course, success was not guaranteed, and Leachco remained a bare-bones outfit for many years. Jamie and Clyde wore many hats—designer, managers, manufacturers, bookkeepers, sales representatives, human-resources managers,

[3] Ex. C, Leach Decl. ¶ 3; Tr., D J. Leach Dep., 13:7–22.
[4] Ex. E, Tr., C. Leach Dep., 31:14–22.
[5] Ex. C, Leach Decl. ¶ 5.
[6] Ex. C, Leach Decl. ¶ 5.
[7] Ex. C, Leach Decl. ¶ 5; Ex. D, Tr., J. Leach Dep., 14:3–12.
[8] Ex. C, Leach Decl. ¶ 5.
[9] Ex. C, Leach Decl. ¶ 7.
[10] Ex. C, Leach Decl. ¶ 6.
[11] Ex. C, Leach Decl. ¶ 7.
[12] Ex. C, Leach Decl. ¶ 8.
[13] Ex. C, Leach Decl. ¶ 9.

custodians, construction managers—to keep the company afloat.[14] They worked hard, pinched every penny, and endured many tight years.[15] In 1991—three years after starting Leachco—Jamie and Clyde's accountant told them they were running out of money and had to close the family business.[16]

But Jamie and Clyde had worked hard and weren't ready to give up. Shortly after meeting with their accountant, Jamie called Walmart, which had declined all of Jamie's previous sales pitches.[17] But this time, Jamie got good news. Walmart wanted to order 20,000 Sit 'N Secures for a one-time promotion—Leachco's largest order to date.[18] Walmart's proposal gave new life to Leachco, but the small company faced a tall task: Walmart wanted the order completed and shipped in only six weeks.[19] As always, Jamie and Clyde went to work. With Walmart's purchase order in hand, Leachco secured bank financing, made special arrangements with suppliers, ramped up production, and completed the manufacturing and shipment on time.[20] Walmart's order and Leachco's relentless efforts turned the Company's financial situation around.[21]

Leachco survived. And slowly it grew. Leachco added employees and buildings—its footprint in downtown Ada increased from a small office to nine facilities.[22]

---

[14] Ex. C, Leach Decl. ¶ 10.
[15] Ex. C, Leach Decl. ¶ 11.
[16] Ex. C, Leach Decl. ¶ 11.
[17] Ex. C, Leach Decl. ¶ 12.
[18] Ex. C, Leach Decl. ¶ 12.
[19] Ex. C, Leach Decl. ¶ 12.
[20] Ex. C, Leach Decl. ¶ 12.
[21] Ex. C, Leach Decl. ¶ 12.
[22] Ex. F, Tr., A. Leach Dep., 223:14–224:2.

Leachco has sold its products through Bed Bath & Beyond, Buy Buy Baby, Toys 'R Us, Babies 'R Us, Amazon, QVC, and other retailers.[23]

Even with all its success, Leachco remains a family business. Jamie and Clyde's children Alex, Andrew, and Mabry have worked in just about every capacity—from sweeping floors to removing trash to packaging products to running the company.[24] Alex has worked in all of Leachco's nine buildings at one time or another and currently serves as Leachco's COO.[25] Andrew, too, worked in different jobs over the years and is now Leachco's Controller.[26] Mabry started out working on the production floor and later worked full-time as a receptionist.[27] She currently heads up Leachco's customer service department, and her husband Steve serves as Leachco's CFO.[28] Now, the third generation is getting its start, as Jamie and Clyde's granddaughter has worked in the office and modeled for Leachco's marketing department.[29]

Jamie and Clyde see Leachco as their American Dream: through hard work, innovation, sacrifice, and perseverance, they built a successful small business in their hometown. They've always modeled these virtues for their children and hope to pass on a thriving business.[30] They also feel obligated to sustain the business and find enough work for Leachco's approximately 30 full-time employees.

---

[23] Ex. C, Leach Decl. ¶ 14.
[24] Ex. C, Leach Decl., ¶ 15; Ex. F, Tr., A. Leach Dep., 18:21–19:8.
[25] Ex. C, Leach Decl., ¶ 15; Ex. F, Tr., A. Leach Dep., 223:14–224:22.
[26] Ex. C, Leach Decl. ¶ 15.
[27] Ex. C, Leach Decl. ¶ 15.
[28] Ex. G, Tr., M. Ballard Dep., 17:4–6; Ex. C, Leach Decl. ¶ 15.
[29] Ex. C, Leach Decl. ¶ 19.

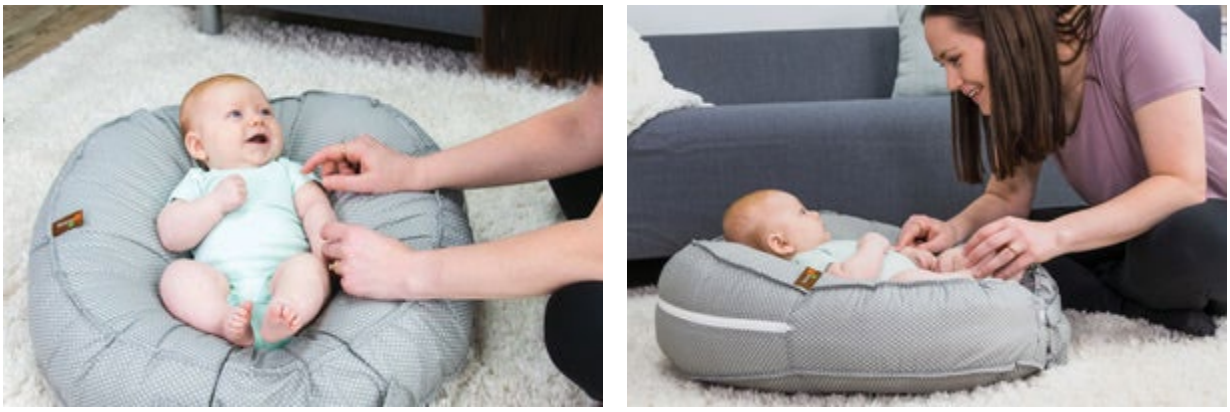
The CPSC has turned this American Dream into a nightmare. Indeed, the CPSC's actions threaten everything Jamie and Clyde created. After the Commission publicly accused Leachco of making a hazardous product, large retailers like Amazon, Buy Buy Baby, and Bed Bath and Beyond stopped carrying the Podster.[31] The Commission's allegations have also harmed Leachco's good name and exemplary safety record—both of which the Leaches earned over three decades of careful designs, hard work, express warnings, honest dealings, and quality craftsmanship.[32] Because of the Commission's public allegations, Leachco's revenues decreased and the company incurred significant legal expenses.[33] Among other measures, Clyde and Jamie are forgoing salaries and living off savings to ensure Leachco remains solvent and its employees have jobs.[34]

THE PODSTER

The Podster—developed and patented in 2008—is just one of the hundreds of products that Leachco has designed and manufactured for families and caregivers.[35] The Podster is a lounger that allows a caregiver to place an infant in a reclined position during supervised, awake time.[36] The patented design features a sling seat with adjustment tabs allows for a custom fit.[37] Jamie designed the Podster to help with

[31] Ex. C, Leach Decl. ¶ 18.
[32] Ex. C, Leach Decl. ¶ 18.
[33] Ex. C, Leach Decl. ¶ 18.
[34] Ex. C, Leach Decl. ¶ 18.
[35] Ex. C, Leach Decl. ¶ 19.
[36] Ex. C, Leach Decl. ¶ 19.
[37] Ex. C, Leach Decl. ¶ 19.

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.[38]



The Podster. *See* https://leachco.com/products/podster (last visited May 31, 2023).

As the Commission acknowledges, Leachco provides express warnings and instructions about the proper use of the Podster.[39] The Commission concedes that the Podster (1) "contains warnings that [it] should not be used for sleep and that adult supervision is always required;"[40] (2) "contains warnings that the product should only be used on the floor, and not in another product, such as a crib, on a bed, table, playpen, counter, or any elevated surface;"[41] (3) "contains warnings that infants should not be placed prone or on their side in the product;"[42] (4) "contains instructions that it should be used for infants not to exceed 16 pounds, and should not be used if an infant can roll over."[43] [redacted],[44] and that

[38] Ex. C, Leach Decl. ¶ 19.
[39] Ex. A, Compl., ¶¶ 13–19; Ex. B, Ans., ¶¶ 12–18.
[40] Ex. A, Compl., ¶15; Ex. B, Leachco Ans., ¶ 14; Ex. H, CPSC Supp. Resp. to Leachco RFA, Nos. 110, 111.
[41] Ex. A, Compl., ¶16; Ex. B, Leachco Ans., ¶ 15; Ex. H, CPSC Supp. Resp. to Leachco RFA, Nos. 112, 114, 115.
[42] Ex. A, Compl., ¶17; Ex. B, Leachco Ans., ¶ 16.
[43] Ex. A, Compl., ¶18; Ex. B, Leachco Ans., ¶ 17; Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 234
[44] Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 113.

the Podster "contains warnings and instructions that use of the product in contravention of these warnings could result in serious injury or death."[45] The Commission does not allege that Leachco's warnings are defective. Rather, as discussed below, the Commission alleges that the Podster is defective "despite" Leachco's warnings and instructions.

UNSAFE-SLEEP ENVIRONMENTS

As the Commission alleges in its Complaint, the Podster "is not and never has been advertised by [Leachco] as a sleep product."[46] Accordingly, the Podster is not an inclined sleeper for infants, *i.e.*, a product "with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old." 15 U.S.C. § 2057d(b). These points are critical for two reasons. First, Congress recently banned inclined sleepers for infants. *See id.* § 2057d(a). Because the Podster is not an inclined sleeper for infants, it is not covered by that ban. Second, as the Commission acknowledges, Leachco expressly warned consumers that the Podster was never to be used for sleep.

Further, the Commission never adopted a consumer product safety rule to regulate the Podster or any infant lounger. *See* 15 U.S.C. § 2052(a)(6) (defining consumer product safety rule). In contrast, the Commission has adopted consumer product safety rules for other infant products, including cribs,[47] high chairs,[48] infant-bouncer

[45] Ex. A, Compl., ¶19; Ex. B, Leachco Ans., ¶ 18; Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 113.
[46] Ex. A, Compl., ¶14; Ex. B, Leachco Ans., ¶13.
[47] 16 C.F.R. pt. 1219, Safety Standard for Full-Size Baby Cribs; *id.* pt. 1220, Safety Standard for Non-Full-Size Baby Cribs.
[48] 16 C.F.R. pt. 1231, Safety Standard for High Chairs.

seats,[49] car seats,[50] and (before they were banned) inclined infant sleepers.[51] Thus, the Commission does not, and cannot, allege that the Podster violates a consumer product safety rule.

The Commission, however, claims that the Podster presents a "substantial product hazard." 15 U.S.C. § 2064(a)(2). This claim rests on isolated instances of unsafe-sleep environments—environments that run afoul of "safe sleep" guidelines promoted by the CPSC, other government agencies, and organizations like the American Academy of Pediatrics.[52] Consistent with the Podster's warnings and instructions, the CPSC and National Institutes for Health (NIH) recommend the following to ensure a "safe sleep environment"—

> [CPSC]
>
> 1. *Back to Sleep:* Always place the baby to sleep on their back to reduce the risk of sudden unexpected infant death syndrome (SUID/SIDS) and suffocation.
> 2. *Bare is Best:* Always keep the baby's sleep space bare (fitted sheet only) to prevent suffocation. Do not use pillows, padded crib bumpers, quilts or comforters.
> 3. Transfer the baby to a firm, flat crib, bassinet, play yard or bedside sleeper if they fall asleep in a swing, bouncer, lounger, or similar product.

---

[49] 16 C.F.R. pt. 1229, Safety Standard for Infant Bouncer Seats.

[50] 16 C.F.R. pt. 1225, Safety Standard for Hand-Held Infants Carriers.

[51] *See* Safety Standard for Infant Sleep Products, 86 Fed. Reg. 33022 (June 23, 2021). Pursuant to the Safe Sleep for Babies Act of 2021, P.L. 117-126, "inclined sleepers for infants" became banned hazardous products (effective Nov. 12, 2022) under the Consumer Product Safety Act. 15 U.S.C. § 2057. An "inclined sleeper for infants" is defined as a product "with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old." *Id*. § 2057d(b).

[52] *See, e.g.*, https://www.cpsc.gov/SafeSleep; https://www.cdc.gov/reproductivehealth/features/baby-safe-sleep/index.html; https://safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment; https://www.aap.org/en/patient-care/safe-sleep/; https://www.aap.org/en/patient-care/safe-sleep/, all last visited June 8, 2023.

4. Inclined products, such as rockers, gliders, soothers, and swings should never be used for infant sleep, and infants should not be left in these products unsupervised, unrestrained, or with soft bedding material, due to the risk of suffocation.[53]

[NIH] Babies should never sleep on an adult bed, couch, or armchair by themselves, with others, or with pets.[54]

The CPSC noted that its "latest nursery product injury and death report shows most nursery-product infant deaths occurred in a cluttered sleep space, when soft bedding was added to the cribs, playpens/play yards or bassinets/cradles."[55] For example, according to the CPSC report, between 2017 and 2019, 137 deaths were associated with cribs and mattresses[56]—products that are subject to CPSC consumer product safety rules.[57] And almost three-fourths of these deaths "were associated with a cluttered sleep environment (the presence of extra bedding in the crib, such as pillows, blankets, and/or comforters, among others)."[58]

[redacted]

[53] *See* https://www.cpsc.gov/Newsroom/News-Releases/2023/Whether-At-Home-or-Traveling-for-the-Holidays-CPSC-Reminds-Parents-to-Keep-Babies-Sleep-Space-Safe, last visited June 8, 2023. A copy is attached as Ex. Z.

[54] *See* https://safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment, last visited June 8, 2023. A copy is attached as Ex. AA.

[55] *See* Ex. Z (linking to https://www.cpsc.gov/s3fs-public/Nursery-Products-Annual-Report-2022.pdf?VersionId=48HfEaAG2znYilGMU6I9EC.z8UMAe4Oy). A copy of the CPSC's Nursery-Products Report is attached as Ex. BB.

[56] Ex. BB, Injuries and Deaths Associated with Nursery Products Among Children Younger than Age Five (Nov. 2022) at 9.

[57] 16 C.F.R. pt. 1219, Safety Standard for Full-Size Baby Cribs; *id.* pt. 1220, Safety Standard for Non-Full-Size Baby Cribs; *id.* pt. 1241, Safety Standards for Crib Mattresses.

[58] Ex. BB, Injuries and Deaths Associated with Nursery Products Among Children Younger than Age Five (Nov. 2022) at 9–10.

[redacted]

[59] The Commission conducted an IDI for each of the incidents at issue.

[60] Ex. I, Alabama Daycare IDI [Dep. Ex. 10], CPSC0000041.

[61] Ex. I, Alabama Daycare IDI [Dep. Ex. 10], CPSC0000041, 49, 57, 58, 63, 74, 10270. The term "pillow" is a misnomer, as a pillow is a distinct product from an infant lounger, and Leachco has never described the Podster as a pillow. [redacted] As Leachco explains below, the Commission here dispenses with its otherwise careful definition of consumer products.

[62] Ex. I, Alabama Daycare IDI [Dep. Ex. 10], CPSC0000041.

[63] Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 196; Ex. I, Alabama Daycare IDI [Dep. Ex. 10], CPSC0000041, 63, CPSC0010270; Ex. J, Tr., V. Baulding Dep., 111:4–12 [CPSC0003226].

[64] Ex. I, Alabama Daycare IDI, CPSC0000041 [Dep. Ex. 10].

[65] Ex. I, Alabama Daycare IDI, CPSC0000041 [Dep. Ex. 10].

[66] *See* Ex. A, Compl., ¶¶ 15–19, 21–22.

[redacted]

[67] Ex. I, Alabama Daycare IDI, CPSC0000041 [Dep. Ex. 10].
[68] Ex. I, Alabama Daycare IDI, CPSC0000049–51 [Dep. Ex. 10].
[69] Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 196; Ex. I, Alabama Daycare IDI, CPSC0000049–51 [Dep. Ex. 10].
[70] Ex. K, Bed-Sharing IDI, CPSC0000142 CPSC0010360 [Dep. Ex. 16].
[71] Ex. K, Bed-Sharing IDI, CPSC0000142, CPSC0010360 [Dep. Ex. 16].
[72] Ex. K, Bed-Sharing IDI, CPSC0000142 [Dep. Ex. 16].
[73] Ex. K, Bed-Sharing IDI, CPSC0000142 [Dep. Ex. 16].
[74] Ex. K, Bed-Sharing IDI, CPSC0000142 [Dep. Ex. 16].
[75] Ex. L, Virginia Daycare IDI [Dep. Ex. 18].
[76] Ex. L, Virginia Daycare IDI, CPSC0010501–03 [Dep. Ex. 18].

[redacted]

THE COMMISSION'S "INVESTIGATION"

Before the Commission filed it administrative complaint in February 2022,

[redacted]

[77] Ex. L, Virginia Daycare IDI, CPSC0010501–03 [Dep. Ex. 18].
[78] Ex. L, Virginia Daycare IDI, CPSC0010505 [Dep. Ex. 18].
[79] Ex. L, Virginia Daycare IDI, CPSC0010503 [Dep. Ex. 18]; CPSC0010878.
[80] Ex. L, Virginia Daycare IDI, CPSC0010504 [Dep. Ex. 18].
[81] Ex. L, Virginia Daycare IDI, CPSC0010504 [Dep. Ex. 18].
[82] Ex. H, CPSC Supp. Resp. to Leachco RFA, Nos. 279–284.
[83] *See* Ex. M, PSA No. 0598.21 (Foster PSA) p. 1 [Dep. Ex. 1]; Ex. N, PSA No. 0600.21 (Wanna-Nakamura PSA) p. 1 [Dep. Ex. 11]; Ex. O, PSA No. 0597.21 (Nesteruk PSA) p. 1 [Dep. Ex. 15]; Ex. P, Nesteruk Dep.,43:16–44:15.
[84] Ex. Q, Foster Dep., 79:1–20; Ex. R, Wanna-Nakamura Dep., 50:11–23; Ex. P, Nesteruk Dep., 65:18–22.

[redacted]

[85] Ex. M, PSA No. 0598.21 (Foster PSA) [Dep. Ex. 1]; Ex. Q, Foster Dep., 35:10–12.

[86] Ex. N, PSA No. 0600.21 (Wanna-Nakamura PSA) [Dep. Ex. 11]

[87] Ex. O, PSA No. 0597.21 (Nesteruk PSA) [Dep. Ex. 15]; Ex. P, Nesteruk Dep., 41:13–15.

[88] Ex. Q, Foster Dep., 86:6–21; Ex. R, Wanna-Nakamura Dep., 18:25–19:6, 34:15–21; Ex. P, Nesteruk Dep., 48:5–15.

[89] Ex. Q, Foster Dep., 86:6–21; Ex. R, Wanna-Nakamura Dep., 18:3–19:4, 34:15–21; Ex. P, Nesteruk Dep., 62:13–16, 132:21–23. [redacted] *See, e.g.*, Ex. I, Alabama Day Care IDI, p. 1 (CPSC0000040) [CSPC Dep. Ex. 10]; Ex. Q, Foster Dep. 58:5–59:4.

[90] Ex. Q, Foster Dep., [redacted]

[91] Ex. Q, Foster Dep., 174:23–175:7.

[92] Ex. Q, Foster Dep., 96:4–9, 112:1–6, 130:3–6, 20–24, 131:15–18, 137:6–11, 173:4–9, 175:23–177:9; 186:25–187:5.

[redacted]

[93] Ex. M, PSA No. 0598.21 (Foster PSA), p. 14 (CPSC0000029) [Dep. Ex. 1]; Ex. Q, Foster Dep., 180:5–8.

[94] Ex. Q, Foster Dep., 180:18–19.

[95] Ex. M, PSA No. 0598.21 (Foster PSA), p. 14 (CPSC0000029) [Dep. Ex. 1].

[96] Ex. Q, Foster Dep., 180:20–181:12. *See id.* 178:23–179:5 [redacted] *see also id.* 177:10–186:2.

[97] Ex. N, PSA No. 0600.21 (Wanna-Nakamura PSA), p. 4 (CPSC0000036) [Dep. Ex. 11].

[redacted]

[98] Ex. R, Wanna-Nakamura Dep., 41:3–8 (emphasis added).
[99] Ex. R, Wanna-Nakamura Dep., 41:18–42:2.
[100] Ex. R, Wanna-Nakamura Dep., 41:9–17.
[101] Ex. P, Nesteruk Dep., 85:7–18.
[102] Ex. O, PSA No. 0597.21 (Nesteruk PSA, p. 5 (CPSC0000010) [Dep. Ex. 15].
[103] Ex. P, Nesteruk Dep., 106:2–107:12.
[104] Ex. P, Nesteruk Dep., 107:13–14.
[105] *See* Ex. O, PSA No. 0597.21 (Nesteruk PSA) pp. 2–10 (CPSC0000007–15) [Dep. Ex. 15]; Ex. P, Nesteruk Dep., 48:21–50:1.
[106] Ex. P, Nesteruk Dep., 80:6–81:1.

[redacted]

THE COMMISSION'S ALLEGATIONS

The Commission asserts one count—that the Podster is a "substantial product hazard" under the CPSA.[112] The Commission acknowledged that the Podster "is not and has never been advertised by [Leachco] as a sleep product" and that the Podster came with express warnings against using the Podster for sleep, placing the Podster

[107] Ex. P, Nesteruk Dep., 49:8–11.
[108] Ex. P, Nesteruk Dep., 81:9–83:12.
[109] Ex. P, Nesteruk Dep., 90:13–21.
[110] Ex. P, Nesteruk Dep., [redacted]
[111] Ex. P, Nesteruk Dep., [redacted]
[112] Ex. A, Compl., Count I.

in a crib or on any elevated surface, bedsharing, using the Podster with infants over 16 pounds or infants who can roll over.[113]

But, the Commission claims, despite these warnings, "it is foreseeable" that consumers "may" misuse the Podster. For example, the Commission alleges that caregivers "may trust that the products are safe places to leave infants" or "may" leave a sleeping infant in a Podster; consumers "who are traveling or who are dealing with significant financial hardship may be more likely to" allow an infant to sleep in a Podster; and unsupervised infants "can" roll or move off the Podster.[114] The Commission asserts that the design of the Podster is defective because, *e.g.*, it allegedly "facilitates" an infant's movement on the Podster, which purportedly "enhance[es]" some undefined and indeterminate "risk that the infant's nose and mouth will be obstructed" by the Podster or by another object such as soft bedding.[115] The Commission also claims the Podster is defective because it "may be attractive to caregivers who wish to bedshare with an infant."[116]

The Commission then alleges that the Podster poses a "substantial risk of injury" because of the (allegedly) foreseeable misuses.[117] This "foreseeable misuse" standard arises not from the text of the CPSA (15 U.S.C. § 2064(a)(2)) but from a nonbinding, interpretative regulation (16 C.F.R. 1115.4), which applies (if at all) to a statute not at issue here (15 U.S.C. § 2064**(b)**).[118] According to the CPSA, a

[113] Ex. A, Compl., ¶¶14–19.
[114] Ex. A, Compl., ¶¶20(a), (b), (d), 21.
[115] Ex. A, Compl., ¶¶27–28.
[116] Ex. A, Compl., ¶32; *see also id*. ¶33.
[117] Ex. A, Compl., ¶¶38–41.
[118] Ex. A, Compl., ¶¶44–45, 46; *see also* Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 275 [redacted]

"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).[119] But the Commission alleges that the Podster "contains defects because it is foreseeable" that consumers will misuse it and because, *e.g.*, the Podster's design "may lead to it being used for bedsharing, which can facilitate an infant's rolling off the product…."[120]

The Commission asks for a determination that the Podster presents a "substantial product hazard" and that public notice is required to adequately protect the public.[121] The Commission also seeks an order compelling Leachco to conduct a recall, refund purchasers, and pay damages to third parties who incur recall-related costs.[122]

STANDARD OF REVIEW

A party may move "for a Summary Decision and Order in its favor upon all or any of the issues in controversy." CPSC Rules of Practice for Adjudicative Proceedings, 16 C.F.R. 1025.25(a). The 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." *Id*. § 1025.25(c); *see also* 45 Fed. Reg. 29,206, 29,206 (May 1, 1980) (CPSC's Rules of Practice are "patterned on the Federal Rules of Procedure").

---

[119] *See* Ex. A, Compl., ¶44.
[120] Ex. A, Compl., ¶¶20, 20(e).
[121] Ex. A, Compl., Relief Sought ¶¶A, B.
[122] Ex. A, Compl., Relief Sought ¶C.

The movant bears the initial burden of identifying those portions of the record that show a lack of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A fact is material if it "might affect the outcome of the suit under the governing law," and a dispute is genuine if "the evidence is such that a reasonable [factfinder] could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The nonmoving party must thereafter "designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex Corp.*, 477 U.S. at 324 (quoting Fed. R. Civ. P. 56(e)).

Because the non-movant must supply evidence that, if true, would allow a reasonable trier of fact to find in its favor, a "mere . . . scintilla of evidence in support of" the non-movant's position cannot defeat a motion for summary judgment. *Anderson*, 477 U.S. at 252. Thus, courts grant summary judgment when the non-movant's evidence is "merely colorable, or is not significantly probative." *Id.* at 249–50 (citations omitted).

SUMMARY OF ARGUMENT

Under the Consumer Product Safety Act, the Commission may order a manufacturer to take remedial action only if it proves a consumer product "presents a substantial product hazard." 15 U.S.C. § 2064(c)-(d). The Act defines a "substantial product hazard" as "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." *Id.* § 2064(a)(2).

Thus, before the Commission can force Leachco to take remedial action, it must prove (1) the Podster is a defective product (2) that causes (3) a substantial risk of injury to the public. *See Zen Magnets*, CPSC Dkt. 12-2, No. 163, 2017 WL 11672449, at *8 (CPSC Oct. 26, 2017) ("To find a substantial product hazard under Section 15(a)(2) of the CPSA, the Commission must conclude that: the Subject Products contain a defect; and such defect, 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.").[123]

Under the undisputed material facts, the Commission cannot meet its burden to establish these statutory elements. *First*, the Commission has not proven that the Podster is or has a "product defect." 15 U.S.C. § 2064(a)(2). Instead, the Commission tries to rewrite the statute, cobble together disparate factors, and create a new theory of "substantial product hazard." This argument has no basis in law.

Second, even if the Commission's view were correct and the Podster contains a "product defect," the agency still cannot show that the "defect" "*created*" a "substantial risk of injury to the public." There is no evidence in the record showing that the Podster was the factual or proximate cause of any injury alleged by the Commission to show "a substantial risk of injury."

Third, even if the Commission could prove the Podster contains a product defect that creates a risk of injury, there is still no "*substantial* risk of injury to the public" because the risk of injury from the Podster is statistically nonexistent.

[123] *See also* Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 24 [redacted]

Fourth, if the Commission's interpretation of what constitutes a "product defect" or "a substantial risk of injury" is correct, then the CPSA violates the major questions doctrine, the nondelegation doctrine, and because it is void for vagueness, the due process clause.

Finally, Leachco preserves its arguments concerning other constitutional violations.

At bottom, under the undisputed material facts, the Commission has not met its burden to prove the Podster is a "substantial product hazard." Leachco is entitled to a summary decision as a matter of law.

I. THE COMMISSION CANNOT ESTABLISH A DEFECT UNDER THE CONSUMER PRODUCT SAFETY ACT

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." 15 U.S.C. § 2064(a)(2).[124] The term "product defect" is undefined and, therefore, it must take on its traditional meaning—which is a manufacturing, design, or warning/marketing defect. The Commission, however, claims that a "product defect" is foreseeable consumer misuse. This irrational definition (which, since misuse is ubiquitous, would make every product defective) is based on 16 C.F.R. 1115.4. But this regulation is non-binding, interpretive guidance that by its own terms applies to an irrelevant section of the CPSA (§ 2064**(b)**). The Court must reject the Commission's attempt to redefine the law.

[124] Ex. H, CPSC Supp. Resp. to Leachco's RFAs, Nos. 24, 98–99 [redacted]

A. The Term "Product Defect" in the CPSA Means Manufacturing Defect, Design Defect, or Warning/Marketing Defect

The statutory text controls. *Sebelius v. Cloer*, 569 U.S. 369, 376 (2013); *see Sackett v. EPA*, No. 21-454, 2023 WL 3632751, at *10 (U.S. May 25, 2023) ("We start, as we always do, with the text."). This is because "only the words on the page constitute the law adopted by Congress and approved by the President." *Bostock v. Clayton Cnty.*, 140 S.Ct. 1731, 1738 (2020); *see id.* ("If judges could add to, remodel, update, or detract from old statutory terms inspired only by extratextual sources and our own imaginations, we would risk amending statutes outside the legislative process reserved for the people's representatives."). Further, undefined "statutory terms are generally interpreted in accordance with their ordinary meaning." *BP Am. Prod. Co. v. Burton*, 549 U.S. 84, 91 (2006). And when the text's meaning is clear, the inquiry ends. *Puerto Rico v. Franklin California Tax-Free Tr.*, 579 U.S. 115, 125 (2016). "Interpreters should not be required to divine arcane nuances or to discover hidden meanings." ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 69 (2012)

Here, the CPSA does not define "product defect." Courts thus employ the "'common practice of consulting dictionary definitions to clarify their ordinary meaning." *United States v. TRW Rifle 7.62X51mm Caliber, One Model 14 Serial 593006*, 447 F.3d 686, 689 (9th Cir. 2006) (quoting *United States v. Carter*, 421 F.3d 909, 911 (9th Cir. 2005)). Dictionaries show that the term "product defect" means "[a]n imperfection in a product that has a manufacturing defect or design defect, or is faulty because of inadequate instructions or warnings. See "*manufacturing defect*;

design defect; *marketing defect*." Product Defect (1967), *Black's Law Dictionary* (11th ed. 2019); *see also* Restatement (Third) of Torts § 2 (Am. L. Inst. 1998) (Third Restatement) ("A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings.").

Courts also look to the common law because when "Congress uses terms that have accumulated settled meaning under the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms." *Neder v. United States*, 527 U.S. 1, 21–22 (1999) (cleaned up). There is no indication in the CPSA that Congress intended to deviate from settled, common-law understandings. *Cf. Zepik v. Tidewater Midwest, Inc.*, 856 F.2d 936, 942 (7th Cir. 1988) ("For our purposes, it is enough to observe that given the CPSA's structure and legislative history no plausible federal standard could deviate so radically from established concepts of causation in tort . . . as to authorize suits under section 23 for reporting violations.").

Therefore, because the CPSA "uses a common-law term, without defining it," the CPSA "adopts its common-law meaning." SCALIA & GARNER 320; *see also id*. ("The age-old principle is that words undefined in a statute are to be interpreted and applied according to their common law meanings.").

Here, the common-law meaning of "product defect" comports with the ordinary dictionary definition. The New York Court of Appeals, for example, held, "[a]s the law has developed thus far, a defect in a product may consist of one of three elements:

mistake in manufacturing; improper design, or by the inadequacy or absence of warnings for the use of the product." *Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 403 N.E.2d 440, 443 (N.Y. 1980) (cleaned up). A leading treatise likewise explained that after § 402A of the Second Restatement was issued, courts and writers began to think that three types of product defect should be distinguished from one another. These were (1) manufacturing defects or production flaws, (2) design defects, and (3) information or warning defects, also called 'marketing' defects." Dan B. Dobbs, Paul T. Hayden, & Ellen M. Bublick, *The Law of Torts* (2d ed. 2023) § 452.

Accordingly, the term "product defect," according to both ordinary, dictionary meaning and the common law, means a manufacturing, design, or warning defect.

B. The Commission Does Not Allege a Manufacturing or Warning Defect

It is undisputed that the Commission is not alleging a manufacturing defect here.[125]

Nor did the Commission allege that the Podster has a warning (or marketing) defect,[126] and, before fact discovery closed, the Commission repeatedly represented that it was not alleging an "inadequate-warnings case."[127] That should resolve this issue, but the Commission tardily tried to introduce evidence that Leachco's warnings were deficient.

---

[125] [redacted]

[126] The complaint states that a "defect *can* also occur in a product's contents, construction, finish, packaging, warnings, or instructions," but it nowhere alleges that Leachco's Podster *is* defective for any of those reasons. Ex. A, Compl., ¶46 (emphasis added). As discussed below, the Commission's claim is that foreseeable consumer misuse renders the Podster defective *despite* Leachco's warnings and instructions. *See* Ex. A, Compl., ¶¶20, 23, 38.

[127] *See* Ex. S, O. Dunford Oct. 25, 2022 E-Mail [redacted]

Most egregiously, the Commission supplemented an interrogatory response—after the close of both fact and expert discovery—which contradicts its previous representation that this case does not involve allegations of inadequate warnings. The interrogatory in question (No. 5) asked the Commission to "[d]escribe in complete detail any warning or instruction you contend Leachco provided improperly or failed to provide in connection with the Podster . . .."[128]

[redacted]

[128] *See* Ex. T, CPSC Fourth Supp. Resp. to Leachco's 1st Set of Interrogatories, CPSC's initial response to ROG No. 5.

[129] Ex. T, CPSC Fourth Supp. Resp. to Leachco's 1st Set of Interrogatories, CPSC Resp. to ROG No. 5.

[130] Ex. T, CPSC Fourth Supp. Resp. to Leachco's 1st Set of Interrogatories, CPSC Resp. to ROG No. 5.

[131] Ex. T, CPSC Fourth Supp. Resp. to Leachco's 1st Set of Interrogatories, CPSC First Supp. Resp. to ROG No. 5.

[redacted]

The Commission's bait-and-switch cannot be tolerated. The Court cannot allow the Commission to fail to make an allegation in its complaint, disclaim the allegation during the fact-discovery process, and then introduce evidence on that claim after the fact-discovery cutoff. The Commission's previous (and consistent) representations that this was not an inadequate-warnings case prevented Leachco from engaging in discovery on that issue. Here (and at the hearing, if this matter proceeds), Leachco is prejudiced by the Commission's last-minute surprise.

Therefore, the Commission should not be allowed to allege that Leachco's warnings or instructions are inadequate, nor should the Commission be allowed to present or rely on any evidence or expert testimony on this issue. Indeed, during its February 24, 2023 conference, this Court warned the parties about the consequences of attempting to rely on materials withheld from discovery:

[redacted]

---

[132] Ex. T, CPSC Fourth Supp. Resp. to Leachco's 1st Set of Interrogatories, CPSC Fourth Supp. Resp. to ROG No. 5. These fourth supplemental responses were served May 11, 2023. *Id.*

[133] The fact-discovery deadline was March 30, 2023. *See* Ex. CC, Order on Prehearing Schedule. On April 28, 2023, the Commission served reports of Celestine Kish, Umakanth Katwa, and Erin Mannen. *See* Exs. V, W. The Commission served a "corrected" version of Ms. Kish's report on May 2, 2023. Ex. X, May 2, 2023 Corrected Kish Report.

[134] Ex. U, Feb. 24, 2023 Hearing Transcript, 33:14–34:5.

This Court's admonition is consistent with well-established practice. *See, e.g.*, 8B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* (3d ed. 2023) § 2289.1 (explaining that sanction prohibiting use of certain matters as evidence "applies not only at trial, but also with respect to any motion, such as a motion for summary judgment, or at a hearing.") (footnote omitted).

In short, the Commission did not allege that the Podster had a manufacturing or a warnings defect, and this Court should not allow the Commission to change its position on warnings at this late hour.

C. The Commission Cannot Show that the Podster is Defectively Designed

While not entirely straightforward (as explained below), the Commission has attempted to allege a design defect. But it cannot carry its burden to show that the Podster in fact has a design defect.

A product is defectively designed only when, "at the time it leaves the seller's hands, [it] is in a condition not reasonably contemplated by the ultimate consumer *and is unreasonably dangerous for its intended use*; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." *Hunter v. Shanghai Huangzhou Elec. Appliance Mfg. Co.*, 505 F. Supp. 3d 137, 152–53 (N.D.N.Y. 2020) (cleaned up) (emphasis added). This well-established understanding recognizes that "[s]ince no product may be completely accident proof, the ultimate question in determining whether an article is defectively designed involves a balancing of the likelihood of harm against the burden of taking precaution against that harm." *Id.* at 153 (cleaned up).

Therefore, a product is "defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe." Third Restatement § 2(b).

Here, however, the Commission does not allege that any "balancing" is required and offers no "balancing" evidence whatsoever. Nor does the Commission allege that the Podster is "unreasonably dangerous for its intended use." *Hunter*, 505 F. Supp. 3d at 152. Further, the Commission makes no allegations and has disclosed no fact or expert evidence showing that the risk of injury from the Podster outweighs its utility or that an alternative design could reduce or avoid the injuries alleged to be caused by the Podster.[135] [redacted]

Instead, the Commission alleges hypothetical contingencies that the Podster's design "may" lead to or "could" cause. For example, the Commission alleges that the Poster's design "may lead to" bedsharing.[137] Similarly, the Commission alleges that the design "facilitates movement off the Podster, which *can* result in an infant's nose and mouth being obstructed by another object in the infant's environment, such as soft bedding."[138] As noted above, Podsters were never designed or intended to be used

[135] Ex. H, CPSC Supp. Resp. to Leachco RFA Nos. 130–13.
[136] Ex. H, CPSC Supp. Resp. to Leachco RFA Nos. 130–135; Ex. T, CPSC Resp. Leachco ROG, Nos. 4, 35.
[137] Ex. A, Compl., ¶50(e).
[138] Ex. A, Compl., ¶50(d) (emphasis added).

for sleep, in cribs, for bedsharing, or with other soft items. *See Hunter*, 505 F. Supp. 3d at 152–53 (explaining that product has design defect only if product is unreasonably dangerous for its intended use). Therefore, the Commission cannot show that the Podster was defectively designed.

D. The Commission Tries to Create a Previously Unknown "Product Defect"

Because the Commission has not alleged or cannot prove that the Podster has a manufacturing, warning, or design defect, it tries to fashion a radical definition of "product defect."[139] It purports to equate *product defect* with *consumer misuse*; *i.e.*, that misuse is itself a defect. The Commission alleges that the Podsters "contain defects because it is foreseeable that caregivers will use the product for infant sleep[,] and it is foreseeable that caregivers will leave infants unattended in the product."[140] This theory has no basis in the text of CPSA (which nowhere says "foreseeable misuse"), traditional tort principles on which the CSPA is based, or any reasonable extrapolation of existing law. While "foreseeable misuse" can be a relevant *factor* in defect cases, "foreseeable misuse" *itself* is not—and cannot be—a stand-alone defect. Under the Commission's new definition, any potential foreseeable misuse would effectively render a consumer product defective.

Long-standing legal principles, however, foreclose the Commission's attempt to radically reformulate what constitutes a "product defect." To repeat, a "product

---

[139] The more appropriate description here might be that the Commission is trying to establish a quasi-defect free regime by "playing fast and loose with the definitions for defect." *See* James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability without Defect*, 66 N.Y.U. L. Rev. 1263, 1296 (1991).
[140] Ex. A, Compl., ¶50.

defect" is a manufacturing, design, or warning defect. "Foreseeable misuse" is a *factor* courts apply when a product is alleged to have defective warnings or design. *See* Third Restatement § 2, comment *p* ("Foreseeable product misuse, alteration, and modification must also be considered in deciding whether an alternative design should have been adopted."); *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 84 (S.D.N.Y. 2001) ("A failure to warn claimant must show (1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm.").

Here, the Commission does not allege a warning defect. And, because the Commission does not allege that the Podster is "unreasonably dangerous for its intended use" (and for the other reasons set forth above, section I.C.), the Commission cannot prove a design defect. Accordingly, the "foreseeable misuse" factor has no bearing whatsoever in this case. In all events, "foreseeable misuse" itself is not a defect.

II. THE COMMISSION CANNOT PROVE CAUSATION

The Commission must prove that, "*because of*" the "pattern of defect, the number of defective products distributed in commerce, the severity of risk, or otherwise," the Podster "*creates* a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2) (emphasis added). As explained below, the terms "because of" and "creates" require the Commission to prove causation. It cannot. Therefore, even if the Podster contains a "product defect," the Commission's claim under § 2064(a)(2) still fails, because the Commission cannot show that any defect *causes* a substantial risk of injury to the public.

As before, when statutory terms are undefined, courts apply their ordinary meanings. Here, "the ordinary meaning of 'because of'" incorporates the standard of but-for causation, *Bostock*, 140 S.Ct at 1739, and the ordinary meaning of "create" is "to bring into existence" or "to cause to be or to produce by fiat or by mental, moral, or legal action" or "to bring about by a course of action or behavior," WEBSTER'S THIRD NEW INT'L DICTIONARY 532 (1993).

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

equivalent to the causal connection *required to establish common law tort liability*.")

(emphasis added).

[redacted]

[141] Ex. I, Alabama Daycare IDI, CPSC0000041, 49, 57, 58, 63, 74, 10270 [Dep. Ex. 10].

[142] Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 196; Ex. I, Alabama Daycare IDI, CPSC0000041, 49, 57, 58, 63, 74, 10270 [Dep. Ex. 10].

[143] Ex. K, Bed-Sharing IDI, CPSC0000142 CPSC0010360 [Dep. Ex. 16].

[redacted]

[144] Ex. K, Bed-Sharing IDI, CPSC0000142 [Dep. Ex. 16].
[145] Ex. K, Bed-Sharing IDI, CPSC0000142 [Dep. Ex. 16].
[146] Ex. L, Virginia Daycare IDI [Dep. Ex. 18].
[147] Ex. L, Virginia Daycare IDI, CPSC0010501–03 [Dep. Ex. 18].
[148] Ex. L, Virginia Daycare IDI, CPSC0010505 [Dep. Ex. 18].
[149] Ex. L, Virginia Daycare IDI, CPSC0010503–04 [Dep. Ex. 18]; CPSC0010878.

[redacted]

---

[150] Ex. P, Nesteruk Dep., 110:13–22.

[151] [redacted]

[redacted], the Commission has no evidence of any injuries even remotely associated with a Podster. The most that the Commission's evidence can therefore show is that some injuries "could" occur.

III. THE PODSTER PRESENTS NO "SUBSTANTIAL RISK OF INJURY TO THE PUBLIC"

Even if the Commission could show that Podster contained a "defect" that "creates" a risk of injury (it cannot), the Commission's claim again fails because the "defect" does not create a "*substantial* risk of injury to the public." 15 U.S.C. § 2064(a)(2) (emphasis added). *See Zen Magnets*, 2017 WL 11672449, at *8 (liability under the CPSA requires the Commission to prove that (1) a defective product (2) causes (3) a substantial risk of injury to the public). The Commission cannot meet this standard because a "*substantial* risk of injury" means a significant likelihood that a product defect will cause an injury. As just discussed, the Podster—assuming it has a defect that causes any risk—presents an infinitesimally small risk of injury. The Com-

[redacted]

mission has no evidence to the contrary. Therefore, the Commission cannot show that the Podster is a substantial product hazard under § 2064(a)(2).

A. A "Substantial" "Risk of Injury" Requires a Significantly High Likelihood of Injury

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). The statute defines "risk of injury" as "a risk of death, personal injury, or serious or frequent illness." *Id*. § 2052(a)(14). But "substantial" remains undefined. Once again, the Court must "turn to its ordinary meaning." *Life Techs. Corp. v. Promega Corp.*, 580 U.S. 140, 146 (2017). As explained below, the ordinary meaning of "substantial" (risk of injury) is significant likelihood (of injury).

"[T]aken in isolation," "substantial" "might refer to an important portion or to a large portion." *Life Techs.*, 580 U.S. at 146. It "may refer either to qualitative importance or to the quantitatively large size." *Id*. Therefore, the Court must look to additional factors. *See Abramski v. United States*, 573 U.S. 169, 179 (2014) (A court "must (as usual) interpret the relevant words not in a vacuum, but with reference to the statutory context, structure, history, and purpose.") (cleaned up).

The context in which "substantial" is used is particularly relevant here. The term "substantial" modifies "risk of injury," a phrase defined in the CPSA as "a risk of death, personal injury, or serious or frequent illness." 15 U.S.C. § 2064(a)(14). Therefore, because the "risk of injury" includes *substantial* or *significant* effects—including, most obviously, death—the phrase "substantial" cannot itself mean *sub-*

stantial or significant injury. If "substantial" were read in that way, § 2064(a)(2) would be redundant—it would define a "substantial product hazard" as a *product defect that creates a* ***substantial/significant*** *risk of* ***substantial/significant*** *injury*.

Further, if "substantial" were read to modify "injury," § 2064(a)(2) would mean precisely the same thing without the word "substantial." It would define "substantial product hazard" as a *product defect that creates* ***a*** *risk of* ***substantial/significant*** *injury*. Put another way, applying "substantial" to the nature of the injury would read "substantial" out of the statute.

But these are implausible readings because statutory "words cannot be meaningless, else they would not have been used." *United States v. Butler*, 297 U.S. 1, 65 (1936); *see also United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933 (2009) (explaining that statutes must be read "in a manner that gives effect to all of their provisions"); *see also Corley v. United States*, 556 U.S. 303, 314 (2009) (holding statutory interpretation cannot make parts of statute "inoperative or superfluous, void or insignificant") (quotations and citation omitted).

Instead, courts "should favor an interpretation that gives meaning to each statutory provision." *Life Techs.*, 580 U.S. at 147. Therefore, to avoid excising the term "substantial" from § 2064 and to give it meaning, "substantial" should be read to mean the likelihood or probability of the risk occurring. This reading is the most natural way to read § 2064: "substantial" modifies not injury, but the *risk* of injury.

This reading also follows well-worn paths taken by courts around the country. Courts examining the same language in defect cases have ruled that "substantial risk

of injury" means that the "[l]egislature was apparently concerned not with the extent of injury but with the *probability* that an injury would occur." *Fredette v. City of Long Beach*, 187 Cal.App.3d 122, 130 n.5 (Cal. Ct. App. 1986) (cleaned up). In other cases, "substantial risk of injury" has been read to mean that "the risk that an injury will result from the condition is substantial." *Cordova v. City of Los Angeles*, 61 Cal.4th 1099, 1110 (2015). But "a condition that creates only a *remote* possibility of injury is not dangerous *even if the extent of injury* that may occur *is substantial*." *Id.* (emphasis added).

More generally, courts routinely read "substantial risk" to mean the significant *probability* of the event occurring. According to the Supreme Court, statutes using the phrase "substantial risk" "gaug[e] the *riskiness* of conduct." *Johnson v. United States*, 576 U.S. 591, 603 (2015) (emphasis added); *see also Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153–54 (2010) (holding "substantial risk" of injury in standing analysis means a "reasonable probability" that the injury will occur); *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (same). When "judicial interpretations have settled the meaning of an existing statutory provision," courts—absent evidence to the contrary—assume the same meaning applies. *Bragdon v. Abbott*, 524 U.S. 624, 645 (1998). No contrary evidence exists here.

In short, statutory clues all point in one direction: "substantial" modifies the "*risk* of injury" and thus means *the level of the risk*—not the seriousness of the injury. On any other reading, "substantial risk of injury" would mean that *any* risk—however small—could satisfy the statute.

B. Additional Evidence Confirms that "Substantial Risk of Injury" Requires a High Probability of Harm

Lest any doubt linger, neighboring subsections of § 2064(a)(2)—although not alleged by the Commission here—confirm that "substantial" means a significantly high likelihood or probability. Under § 2064(a)(1), a "substantial product hazard" is "a failure to comply with an applicable consumer product safety rule . . . which creates a substantial risk of injury to the public." And because (a)(1) and (a)(2) both use the same term—"substantial risk of injury"—in the same subsection, the words must mean the same thing. *Utility Air Reg. Grp. v. EPA*, 573 U.S. 302, 319–20 (2014) ("One ordinarily assumes 'that identical words used in different parts of the same act are intended to have the same meaning.'" (quoting *Envtl. Defense v. Duke Energy Corp.*, 549 U.S. 561, 574 (2007)).

But "substantial risk of injury" as used in (a)(1) *cannot* mean any risk—however remote—of serious injury. Subsection (a)(1) has two prongs, and the first is "a failure to comply with an applicable consumer product safety rule." To promulgate a consumer product safety rule, the Commission must show that the rule will "prevent or reduce an *unreasonable risk of injury*." 15 U.S.C. § 2056(a) (emphasis added); *see also id.* § 2058(d)(1)(B), (f)(3) (requiring Commission to determine whether an "unreasonable risk of injury" exists). Thus, a consumer product safety rule—and by extension, "substantial product hazard" under (a)(1)—already encompasses an "*unreasonable* risk of injury." And the latter phrase, as the Commission has long said, means the "likelihood of injury." *Safety Standard for Magnets*, 87 Fed. Reg. 57,756, 57,770

(Sept. 21, 2022). Therefore, as in § 2064(a)(2), "substantial" in (a)(1) also applies to likelihood of injury—though the latter imposes an even higher standard.

Similarly, Sections 2056(a), 2058, and 2064(a) use the phrase "risk of injury." But they employ different modifiers—in the former two, the Act uses the adjective "unreasonable;" in the latter, "substantial." In all instances, though, the Commission must show some likelihood of a risk of injury.

In short, a "substantial risk of injury to the public" means a substantial or significant *amount of risk*. *Dodd v. United States*, 545 U.S. 353, 357 (2005) (presuming "legislature says what it means and means what it says") (cleaned up).

C. The Commission Cannot Prove a "Substantial Risk of Injury" from the Podster

In short, "substantial" risk of injury must mean (at least) a significantly high probability of injury. But the Commission has disclosed no evidence—none whatsoever—even attempting to quantify the risk of injury to the public. And all data point in the same direction: the probability is miniscule. Leachco has sold over 180,000 Podsters.[152] [redacted]

[152] *See* Ex. A, Compl., ¶10.
[153] *See* Ex. H, CPSC Resp. to Leachco's RFA, No. 294.
[154] *See* Ex. H, CPSC Resp. to Leachco's RFA, No. 280; *id.* No. 281 [redacted]; *id.* Nos. 282–285 (same).

[redacted]

Thus, even assuming that the Podster is a defective product that causes a risk of injury, the undisputed evidence shows unmistakably that the likelihood of harm is infinitesimally small. Consider: If each of the 180,000 Podsters has been used only a single time (an unreasonably low estimate), the injury rate that the Commission links to the Podster is 0.0017 percent (3 / 180,000). In other words, for every 100,000 Podsters sold, the Commission can point to 1.7 injuries. Assuming that each Podster was used only ten times—still, a vast underestimate—the injury rate (3 / 1,800,000) would be 0.0000017, or 0.00017 percent. A realistic estimate of hundreds of uses per Podster would make the injury rate virtually zero. If that vanishingly small injury rate amounts to a "*substantial* risk of injury," then § 2064(a)'s language has no teeth—*any* product in existence can meet that meager standard.

The Commission has no evidence to show a *substantial* risk of injury. [redacted]

[155] Ex. P, Nesteruk Dep., [redacted]

[redacted]

[156] Ex. P, Nesteruk Dep., 110:13–22.
[157] Ex. P, Nesteruk Dep., 121:2–4.
[158] Ex. V, Mannen Report, at 33. [redacted]
See Ex. H, CPSC Supp. Resp. to Leachco RFA, Nos. 266–73.
[159] *See* Ex. V, Mannen Report, at 33; *see id.* at 10 [redacted]
[160] The Mannen report also reveals another example of the Commission's discovery gamesmanship. Throughout discovery, the Commission insisted that information about other products—including inclined sleep products—is irrelevant. [redacted]

The facts, evidence, and data show that injuries even remotely associated with a Podster are exceedingly rare. On the Commission's own facts, the Podster's injury rate is *at most* 0.0017 per cent. [redacted] The plain statutory language of § 2064(a)(2) requires more. It calls for a "substantial" possibility. Because the evidence cannot possibly show a *substantial* risk of injury, the Commission cannot carry its burden under § 2064(a)(2).

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

A. Congress Did Not Give the Commission a Roving License to Ban Lawful Consumer Products.

As explained above, the Commission's theory requires this Court to ignore well-established principles of statutory interpretation and to adopt radically new definitions found nowhere in the CPSA or in traditional legal regimes. As such, this case fits within an all-too-common pattern that has developed in the modern administrative state. By redefining "product defect" and expansively and unreasonably construing "substantial risk of injury," the Commission attempts to "discover in a long-extant

[redacted] Indeed, as noted above, this Court issued a stark warning to the parties that they would be precluded from using withheld discovery. *See also* 8B *Wright & Miller* § 2289.1 (explaining that sanction prohibiting use of certain matters as evidence "applies not only at trial, but also with respect to any motion, such as a motion for summary judgment, or at a hearing.") (footnote omitted).

Leachco intends to move this Court to disregard all evidence and arguments that the Commission disclaimed before fact discovery ended but on which the Commission attempts to belatedly introduce.

statute an unheralded power representing a transformative expansion it its regulatory authority." *West Virginia v. EPA*, 142 S.Ct. 2587, 2610 (2022) (cleaned up). But the Supreme Court has repeatedly held that under the Major Questions Doctrine "Congress [must] speak clearly when authorizing an agency to exercise powers of vast economic and political significance." *Nat'l Fed'n of Indep. Bus. v. OSHA*, 142 S.Ct. 661, 665 (2022).

The implications of the Commission's view of its authority under the CPSA here cannot be understated. If the Commission can find a "product defect" in a consumer product that (1) is perfectly safe as designed for its intended use and (2) contains express warnings against foreseeable misuse, then the Commission's already extensive recall authority will be subject to no limiting principle. But there is nothing in the CPSA that gives the CPSC this kind of "roving commission," *Michigan v. EPA*, 268 F.3d 1075, 1084 (D.C. Cir. 2001), to eliminate insignificant risks at enormous costs. And Congress no doubt would have used much clearer language had it wanted to stretch CPSC's product hazard authority to every consumer good. *See Sackett*, 2023 WL 3632751, at *13 (Congress does not "tuck[] an important expansion to the reach of" a federal agency's power "into convoluted language"—or "hide elephants in mouseholes").

Further, Congress knows how to ban infant products. As recently as last year, Congress—through the people's representatives—banned inclined sleepers for infants. 15 U.S.C. § 2057d. Congress has, for whatever reason, not banned the Podster or similar products. The Commission may think that Congress should do so, but the

Commission's policy position does not give it the prerogative to take the legislative process into its own hands and make new law through administrative adjudication.

Importantly, products subject to actions under § 2064(a)(2) that do not violate any regulatory ban—like the Podster here[161]—are *legal*. As a former Commissioner has explained, under § 2064(a)(2), "the Commission seeks to remove an *otherwise legal* product from the marketplace." Robert Adler & Andrew F. Popper, *The Misuse of Product Misuse: Victim Blaming at its Worst*, 10 Wm. & Mary Bus. L. Rev. 337, 355 n.94 (2019) (emphasis added). Therefore, if Congress intended to give the CPSC power to force a manufacturer to recall a product that has (1) no manufacturing defect, (2) no warning defect, (3) no design defect that renders the product unsafe for its intended use, and (4) an infinitesimally small likelihood of injury—if Congress truly wanted to give the CPSC such vast power, it would have "enacted exceedingly clear language to significantly alter the power of the Government over private property." *United States Forest Service v. Cowpasture River Preservation Ass'n*, 140 S.Ct. 1837, 1849–50 (2020) (cleaned up). The Commission's claim of such authority—to take any consumer product off the market regardless of whether the product ever caused an injury, or without having to prove any likelihood of injury, would constitute authority of "economic and political significance," which "provides a reason to hesitate before concluding that Congress meant to confer such authority." *West Virginia*, 142 S. Ct. at 2608 (cleaned up). Even if the Commission could argue that the CPSA provided "a

[161] [redacted]

vague statutory grant" of power, such a grant "is not close to the sort of clear authorization required by [Supreme Court] precedents." *West Virginia*, 142 S.Ct. at 2614.

Accordingly, the Commission's attempts to rewrite the CPSA and increase its authority must be rejected.

B. If Congress Did Give the Commission a Roving License to Ban Consumer Products, then the CPSA Violates the Nondelegation Doctrine

The Constitution prohibits Congress from giving away its lawmaking powers. *Jarkesy v. SEC*, 34 F.4th 446, 460 (5th Cir. 2022). As Chief Justice Marshall put it, Congress must decide the "important subjects." *Wayman v. Southard*, 23 U.S. (10 Wheat) 1, 43 (1825). Thus, Congress must make "fundamental policy decisions" itself—"the hard choices." *Industrial Union Dept. v. Am. Petroleum Inst.*, 448 U.S. 607, 687 (1980) (Rehnquist, J., concurring in the judgment). And cabining congressional delegations within proper bounds remains "vital to the integrity and maintenance" of the Constitution's structure. *Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1982); *see also Gundy v. United States*, 139 S. Ct. 2116, 2133 (2019) (Gorsuch, J., dissenting).

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

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

Under that doctrine, the statutory text must provide an "intelligible principle" to properly direct executive agencies. *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 472–73 (2001). In *Panama Refining Co. v. Ryan*, the Supreme Court found a provision of the National Recovery Act unconstitutional because it gave unfettered discretion to the President to decide whether and under what conditions to prohibit the transport of hot oil. 293 U.S. 388, 430 (1935). Notwithstanding the law's general goal of improving American economic conditions, it was ruled unconstitutional because Congress failed to make any policy decision. *Id*. at 416–18. Instead, Congress allowed the President to weigh competing policy considerations as he deemed "fit." *Id*. at 415.

Here, the Court should reject the Commission's interpretation that the CPSA grants it unfettered discretion to (re-)define "product defect" and "substantial risk of injury" as it deems fit. Agencies may fill in details with "judgments of degree," *Whitman*, 531 U.S. at 475 (cleaned up), but Congress cannot allow agencies to set "the criteria against which to measure" their own decisions, *Gundy*, 139 S. Ct. at 2141 (Gorsuch, J., dissenting). Instead, Congress must be "sufficiently definite and precise" so courts can easily determine when an agency exceeds its authorized power. *Yakus v. United States*, 321 U.S. 414, 426 (1944).

The Constitution therefore demands "substantial" guidance for standards that would—under the Commission's interpretation—have the potential to "affect the entire national economy." *Whitman*, 531 U.S. at 475; *see also Michigan v. EPA*, 576 U.S. 743, 762 (2015) (Thomas, J., concurring) (noting "potentially unconstitutional delegation[]" if EPA had unfettered discretion over "which policy goals" it pursued).

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

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

C. Defining "Product Defect" to Allow the Commission to Ban Products Based on "Foreseeable Misuse," Despite Warnings and Instructions, Makes the CPSA Unconstitutionally Vague

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

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

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

But worse, the Commission erroneously relies on 16 C.F.R. 1115.4.[162] Section 1115.4 is [redacted] merely an interpretive rule. And "interpretive rules, even when given *Auer* deference, do *not* have the force of law." *Kisor v. Wilke*, 139 S.Ct. 2400, 2420 (2019) (plurality op.) (citing *Perez v. Mortgage Bankers Ass'n*, 572 U.S. 92, 97 (2015) ("Interpretive rules do not have the force and effect of law and are not accorded that weight in the adjudicatory process.") (cleaned up)). Therefore, an "interpretive rule itself never forms the basis for an enforcement action—because such a rule does not impose any legally binding requirements on private parties." *Id*. (cleaned up). Further, section 1115.4 by its own terms provides (non-binding) guidance for companies that may be obligated to report potential hazards to the Commission under 15 U.S.C. § 2064**(b)(2)**—which is not at issue here.[164]

But, even if section 1115.4 did apply to § 2064(a)(2) and assuming it is not merely interpretive guidance, section 1115.4 would unlawfully allow the Commission to determine—after the fact—that a product is defective based on a non-exhaustive

[162] *See, e.g.*, Ex. A, Compl., ¶¶45, 47 (citing 16 C.F.R. 1115.4).
[163] Ex. H, CPSC Supp. Resp. to Leachco RFA, No. 275.
[164] *See* Ex. A, Compl., Count I (invoking only 15 U.S.C. § 2064**(a)(2)**).

list of factors that the Commission, at its discretion, may or may not apply.[165] Thus, according to 1115.4, "the Commission and staff will consider *as appropriate*:"

> The utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the obviousness of such risk; the adequacy of warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and *other factors relevant to the determination*.

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

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

Such a regime is even more egregious here because the CPSA threatens criminal sanctions. *See* 15 U.S.C. § 2070. And "where a penal statute could sweep so broadly as to render criminal a host of what might otherwise be considered ordinary activities, [the Supreme Court] ha[s] been wary about going beyond what Congress certainly intended the statute to cover." *Sackett*, 2023 WL 3632751, at *15 (quotation

[165] As explained above, a "defective" product without more does not present a substantial product hazard under § 2064(a)(2). Such a defect must cause a substantial risk of death, injury, or serious or frequent illness. *See* above, Section I.

and citation omitted); *see also WEC Carolina Energy Sols. LLC v. Miller*, 687 F.3d 199, 203–04 (4th Cir. 2012) ("Where . . . our analysis involves a statute whose provisions have both civil and criminal application, our task merits special attention because our interpretation applies uniformly in both contexts. Thus, we follow 'the canon of strict construction of criminal statutes, or rule of lenity.'" (citations omitted)). The Commission's view thus "gives rise to serious vagueness concerns in light of the [CPSA's] criminal penalties," thus implicating the due process requirement that penal statutes be defined "with sufficient definiteness that ordinary people can understand what conduct is prohibited." *Sackett*, 2023 WL 3632751, at *15 (cleaned up).

At bottom, under the Commission's view, neither the statute nor the Commission's regulation provides Leachco with the "fair notice" that is required by our Constitution. *See FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 ("A fundamental principle in our legal system is that laws which regulate person or entities must give fair notice of conduct that is forbidden or required.") (citing *Connally v. General Constr. Co.*, 269 U.S. 385, 391 (1926) ("A statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law.").[166] Because parties regulated under the CPSA cannot "steer between lawful and unlawful conduct," the statute is void for vagueness.

[166] *Cf. Sackett*, 2023 WL 3632751, at *9 ("[M]ost laws do not require the hiring of expert consultants to determine if they even apply to you or your property.").

V. THE COMMISSION AND THIS PROCEEDING SUFFER FROM OTHER CONSTITUTIONAL FLAWS

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

A. The Commission's Structure Violates the Constitution's Separation of Powers

Article II of the Constitution provides "[t]he executive Power shall be vested in a President," who must "take Care that the Laws be faithfully executed." U.S. CONST. art. II, § 1, cl. 1; § 3. Article II thus vests the President with "all" of the executive power. *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2191 (2020). And because the President must rely on subordinates to carry out his constitutional duties, the Constitution gives him "the authority to remove those" subordinates. *Id.*

"Without such power, the President could not be held fully accountable for discharging his own responsibilities; the buck would stop somewhere else." *Id.* (cleaned up). And it would be "impossible for the President to take care that the laws be faithfully executed." *Id.* at 2198 (cleaned up). The "President's power to remove—and thus supervise—those who wield executive power on his behalf follows from the text of Article II, was settled by the First Congress, and was confirmed in the landmark

decision *Myers v. United States*, 272 U.S. 52 [] (1926)." *Seila Law*, 140 S. Ct. at 2191–92.

Here, the President may not remove any CPSC Commissioner except "for neglect of duty or malfeasance in office but for no other cause," 15 U.S.C. § 2053(a), and ALJ Young enjoys multi-level tenure protection. These removal protections violate the Separation of Powers, Article II's vesting of the executive power in the President, and the President's duty to "take Care that the Laws be faithfully executed." U.S. CONST. art. II, § 3.

As a result, the Commission is proceeding unlawfully.

1. CPSC Commissioners, principal officers wielding substantial executive power, are unconstitutionally protected against Presidential removal

The President holds "unrestricted" removal power, subject to only two narrow exceptions:

(1) an exception for inferior officers with limited duties and no policymaking or administrative authority, *Seila Law*, 140 S.Ct. at 2199–2200; and

(2) an exception for principal officers who do not exercise any executive power, *id*. 2198–99 (discussing *Humphrey's Executor v. United States*, 295 U.S. 602 (1935)).

Here, the Commissioners are (1) principal—not inferior—officers (2) who wield significant executive power. As a result, the Commissioners' for-cause removal protection in § 2053(a) is unconstitutional.

The Commission cannot dispute that, as heads of the CPSC, they are principal officers. *Free Enter. Fund v. PCAOB*, 561 U.S. 477, 512–13 (2010); *Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868, 884–86 (1991). Nor can the Commission dispute

that it wields significant executive power. It enforces several laws in addition to the CPSA (15 U.S.C. §§ 2051 *et seq*.); it has extensive investigatory powers (*id*. §§ 2065, 2076(b)(1)–(3), (c)); it may prosecute administrative hearings, as here; and it may initiate civil actions and, with the concurrence of or through the Attorney General, criminal actions (*id*. §§ 2069(a), 2071(a), 2073(b), 2076(b); §§ 2070(a), 2076(b)(7)(B)). And "no real dispute" exists that "law enforcement functions that typically have been undertaken by officials within the Executive Branch" qualify as "executive" power. *Morrison v. Olson*, 487 U.S. 654, 691 (1988); *id.* at 706 (Scalia, J., dissenting) ("Governmental investigation and prosecution of crimes is a quintessentially executive function.").

Humphrey's Executor confirms Leachco's argument. That case involved an agency (the 1935 Federal Trade Commission) that—unlike the Commission here—was "said not to exercise *any* executive power." *Seila Law,* 140 S.Ct. at 2199 (emphasis added). And *Humphrey's Executor* explained that the President's unrestricted removal power recognized in *Myers* applies to "all purely executive officers." *Humphrey's Executor*, 295 U.S. at 628. Finally, *Seila Law* reaffirmed that heads of agencies wielding substantial executive power must be removable at will by the President. 140 S.Ct. at 2199–2207.

In sum, the CPSC's Commissioners are (1) principal (not inferior) officers (2) who exercise substantial, "quintessentially executive power [that was] not considered in *Humphrey's Executor*." *Seila Law*, 140 S.Ct. at 2200. Accordingly, the Commission

is unconstitutionally structured and, as such, is precluded from maintaining this action against Leachco. *Cf. Axon Enter. Inc. v. FTC*, 143 S.Ct. 890 (2023).

2. ALJ Young enjoys unconstitutional multilevel removal protection

ALJ Young, an ALJ with the Federal Mine Safety and Health Review Commission, is an inferior executive officer who exercises significant authority on behalf of the United States.[167] He wields "significant discretion when carrying out important functions" pursuant to the laws of the United States. *Lucia v. SEC*, 138 S.Ct. 2044, 2053 (2018) (cleaned up). *Lucia* held that SEC ALJs were executive officers because of their important functions. *Id*. at 2049. The powers of a CPSC Presiding Officer are virtually indistinguishable from those of an SEC ALJ. For example, a Presiding Officer—like SEC ALJs—has "all powers necessary to" carry out the "duty to conduct full, fair, and impartial hearings," including the power to administer oaths and rule on the admissibility of evidence. 16 C.F.R. 1025.42(a); *compare Lucia*, 138 S. Ct. at 2049, 2053 (describing powers of SEC ALJs). And ALJs of the Mine Commission exercise similar powers. *See* 29 C.F.R. 2700.55, .59, .60(a), .67, .69(a).

Here, ALJ Young enjoys at least two levels of protection from removal. *First*, ALJ Young may not be removed except "for good cause established and determined by the Merit Systems Protection Board [MSPB]" following "[a]n action" brought by "the agency in which the administrative law judge is employed." 5 U.S.C. § 7521(a). *Second*, all officers who could perhaps remove ALJ Young—the CPSC Commissioners, Mine Commissioners, and members of the MSPB—themselves may not be

[167] *See* Order Denying Mtn. to Disqualify [Dkt. No. 30] at 3 (acknowledging "I am an executive officer of the United States").

removed by the President except for cause. 15 U.S.C. § 2053(a); 30 U.S.C. § 823(b); 5 U.S.C. § 1202(d).

Under *Free Enterprise Fund*, this multi-level removal protection is unconstitutional. *Cf. Jarkesy*, 34 F.4th at 463–65 (applying *Free Enterprise Fund* and holding that nearly identical removal protections for SEC ALJs were unconstitutional).

The Commission will likely argue that *Free Enterprise Fund* doesn't control because the Supreme Court there did not expressly invalidate multi-level removal protections for ALJs. But this argument "conflicts with *Free Enterprise Fund*'s reasoning," *Axon*, 143 S.Ct. at 905, and with the reasoning of more recent Supreme Court precedent. *Free Enterprise Fund* squarely held that multi-level tenure protection for inferior executive officers violates the Constitution. 561 U.S. at 484, 486–87. In *Lucia*, the Supreme Court held that ALJs of the SEC are inferior Officers of the United States. 138 S.Ct. at 2053–54. As shown above, ALJ Young exercises substantially the same powers as SEC ALJs. Therefore, ALJ Young's status as an ALJ does not remove him from the holding of *Free Enterprise Fund*. Finally, ALJ Young's adjudicative role does not alter the analysis. As the Supreme Court recently held, administrative patent judges, even though they perform adjudicative functions, are executive officers of the United States. *See United States v. Arthrex*, 141 S.Ct. 1970, 1982 (2021).

In sum, *Free Enterprise Fund*, *Seila Law*, and *Arthrex* establish that the CPSC's ALJ—an inferior executive officer wielding significant authority on behalf of the United States—may not enjoy multi-level removal protection. Therefore, multi-level tenure protection enjoyed by ALJ Young is unconstitutional.

B. CPSA's Political-Affiliation Limit Violates Article II

Under the Appointments Clause, the President has the power, "by and with the Advice and Consent of the Senate," to appoint principal officers of the United States. U.S. CONST. art. II, § 2, cl. 2. The Constitution, outside the Appointments Clause, places no limitations on whom the President may nominate and appoint as principal officers of the United States. CPSC Commissioners are principal officers of the United States. Commissioners of the CPSC are appointed pursuant to 15 U.S.C. § 2053. Under 15 U.S.C. § 2053(c), "Not more than three of the Commissioners shall be affiliated with the same political party." The "political party" limitation in Section 2053(c) unconstitutionally limits the President's Appointments Clause power to nominate and appoint, by and with the advice and consent of the Senate, principal officers of the United States.

C. This Proceeding Deprives Leachco of its Rights to Due Process of Law and to a Hearing in an Article III Court

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

But through this proceeding, the Commission—an agency of the Executive Branch—is unlawfully exercising judicial power against Leachco. The "judicial

power" is the power to "bind parties and to authorize the deprivation of private rights." William Baude, *Adjudication Outside Article III*, 133 Harv. L. Rev. 1511, 1513–14 (2020).

Here, the Commission seeks an order and binding judgment that the Podster presents a "substantial product hazard" under the CPSA.[168] The Commission further seeks an order compelling Leachco to recall the Podster and pay damages to third parties that incur recall-related costs. *Id.* Accordingly, the Commission seeks to deprive Leachco of private rights.

As a result, the Commission must follow common-law procedures—most fundamentally, through an Article III court. *Cf. Stern v. Marshall*, 564 U.S. 462, 482–84 (2011). And only courts of law, through the exercise of judicial power, may issue *judgments* and deprive private parties of private rights. *See Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 219 (1995) ("A judicial Power is one to render dispositive judgments.") (cleaned up).

Finally, the Commission's proceedings violate the ancient maxim—protected by the Due Process Clause—*nemo iudex in causa sua* ("no one should be a judge in his own cause"). *See The Federalist No. 10* (Madison) ("No man is allowed to be a judge in his own cause, because his interest would certainly bias his judgment, and not improbably, corrupt his integrity."). Here, the Commission—which authorized the issuance of the administrative complaint against Leachco—has the authority to make

[168] Ex. A, Compl., Relief Sought.

the final decision whether Leachco has violated the CPSA and should, as a result, recall the Podster and incur significant financial penalties.

In sum, this proceeding denies Leachco its right to a hearing before an Article III court.

D. This Proceeding Deprives Leachco of Its Right to a Trial by Jury

The Seventh Amendment to the Constitution provides: "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved." U.S. CONST. amend. VII. Claims analogous to common law claims that existed at the time of the Seventh Amendment's ratification require a jury. *Curtis v. Loether*, 415 U.S. 189, 194–95 (1974). Further, claims that seek legal remedies require a jury. *Tull v. United States*, 481 U.S. 412, 418–22 (1987). Accordingly, it is "settled law" "that the Seventh Amendment jury guarantee extends to statutory claims unknown to the common law, so long as the claims can be said to 'sound basically in tort,' and seek legal relief." *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 709 (1999) (cleaned up).

Here, the Commission's claim that the Podster presents a "substantial product hazard," under the CPSA is essentially a product-liability claim sounding in traditional tort law; that is, the Commission's claim sounds basically in tort. *See City of Monterey*, 526 U.S. at 729 (Scalia, J., concurring) (noting "[c]ommon-law tort actions" implicate the Seventh Amendment). Additionally, the Commission seeks legal damages. It seeks an order compelling Leachco to pay damages to Podster buyers and to

reimburse third parties, such as retailers, who may incur costs arising out of the Commission's order.[169]

This proceeding, therefore, denies Leachco is constitutional right to a jury trial.

CONCLUSION

Because there are no genuine issues material fact, and because Leachco is entitled to judgment as a matter of law—because the Commission cannot establish that the Podster presents a "substantial product hazard"—this Court should grant Leachco's motion for summary decision. A Proposed Order is attached.

DATED: June 9, 2023.

Respectfully submitted,

JOHN F. KERKHOFF
Ohio Bar No. 0097134
FRANK D. GARRISON
Indiana Bar No. 34024-49
JESSICA THOMPSON
North Carolina Bar No. 48112
Pacific Legal Foundation
3100 Clarendon Boulevard, Suite 1000
Arlington, VA 22201
Telephone: 202.888.6881
Fax: 916.419.7747
JKerkhoff@pacificlegal.org
FGarrison@pacificlegal.org
JLThompson@pacificlegal.org

s/ *Oliver J. Dunford*
OLIVER J. DUNFORD
Florida Bar No. 1017791
Pacific Legal Foundation
4440 PGA Blvd., Suite 307
Palm Beach Gardens, FL 33410
Telephone: 916.503.9060
Fax: 916.419.7747
ODunford@pacificlegal.org

Counsel for Respondent Leachco, Inc.

[169] Ex. A, Compl., Relief Sought.

CERTIFICATE OF SERVICE

I hereby certify that on June 9, 2023, the foregoing was served upon all parties and participants of record as follows:

Honorable Michael G. Young
Federal Mine Safety and Health Review Commission
Office of the Chief Administrative Law Judge
1331 Pennsylvania Ave., N.W., Suite 520N
Washington, D.C. 20004-1710
myoung@fmshrc.gov
cjannace@fmshrc.gov

Alberta Mills
Secretary of the U.S. Consumer Product Safety Commission
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814
amills@cpsc.gov

Mary B. Murphy
Director, Div. of Enforcement & Litigation
U.S. Consumer Product Safety Comm'n
4330 East West Highway
Bethesda, MD 20814
mmurphy@cpsc.gov

Robert Kaye
Assistant Executive Director
Office of Compliance and Field Operations
U.S. Consumer Product Safety Comm'n
4330 East West Highway
Bethesda, MD 20814
rkaye@cpsc.gov

Leah Ippolito, Supervisory Attorney
Brett Ruff, Trial Attorney
Rosalee Thomas, Trial Attorney
Caitlin O'Donnell, Trial Attorney
Michael Rogal, Trial Attorney
Frederick C. Millett, Trial Attorney
Gregory M. Reyes, Supervisory Attorney
Complaint Counsel
Office of Compliance and Field Operations
U.S. Consumer Product Safety Comm'n
Bethesda, MD 20814
lippolito@cpsc.gov
bruff@cpsc.gov
rbthomas@cpsc.gov
codonnell@cpsc.gov
mrogal@cpsc.gov
fmillett@cpsc.gov
greyes@cpsc.gov

s/ *Oliver J. Dunford*
Oliver J. Dunford
Counsel for Respondent Leachco, Inc.

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

[PROPOSED] ORDER

In this proceeding, Complaint Counsel has submitted a Motion for Summary Decision. Respondent Leachco, Inc. has also submitted a Motion for Summary Decision Upon consideration of the motions and related memoranda, as well the declarations, affidavits, statements of undisputed facts, and oral argument relating these materials, it is hereby:

ORDERED, that Complaint Counsel's Motion for Summary Decision is **DENIED**; and further

ORDERED that Leachco's Motion for Summary Decision is **GRANTED**; and further

ORDERED that this **Order**, along with the accompanying Memorandum Opinion, shall constitute the Initial Decision and Order in accordance with the provisions of 16 C.F.R. §§ 1025.25; and further

ORDERED that Leachco's Podster, as a matter of law, does not present a "substantial product hazard" under the Consumer Product Safety Act, as amended, 15 U.S.C. § 2051 *et seq*.; and further

ORDERED that a copy of this Order and accompanying Memorandum Opinion shall be entered on the docket and proceedings before the Presiding Officer are terminated.

Dated: _____

_____
Hon. Michael G. Young
Administrative Law Judge