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July 6, 2023

In the Matter of

LEACHCO, INC., CPSC Docket No. 22-1

Respondent.

ORDER DENYING COMPLAINT COUNSEL'S MOTION FOR PARTIAL SUMMARY DECISION
ORDER DENYING RESPONDENT'S MOTION FOR SUMMARY DECISION

Complaint Counsel moves for partial summary decision on the following issues: "(1) it is foreseeable that consumers will use the Leachco, Inc. Podster for infant sleep; (2) it is foreseeable that consumers will use the Podster without constant supervision; and, (3) as a result, the Podster presents a substantial risk of injury." Compl. Counsel's Mot. for Partial Summ. Decision, at 1 (June 9, 2023) ("Compl. Counsel Mot.").

Respondent opposes the motion, asserting Complaint Counsel improperly requests summary decision on whether there is a substantial risk of injury based on a misreading of the statute and without relation to whether a defect exists to cause such risk. *See* Leachco, Inc.'s Br. in Opp'n to CPSC's Mot. for Partial Summ. Decision, at 1–2 (June 23, 2023) ("Resp't Opp'n"). It also asserts Complaint Counsel improperly applies reasonably foreseeable misuse to its claim. *Id.* at 2–3.

Concurrently, Respondent moves for summary decision based on the following contentions: (1) the Commission cannot show the Podster is defective; (2) assuming a defect is found, no evidence demonstrates it creates a substantial risk of injury; and (3) the Commission erroneously contends "substantial risk of injury" means "risk of substantial injury." *See* Leachco, Inc.'s Mot. for Summ. Decision & Memo. in Supp., at 1–2 (June 9, 2023) ("Resp't Mot.").[1]

[1] Respondent also contends that if the Commission's interpretations are correct, then the CPSA violates the Major Questions Doctrine, the Nondelegation Doctrine, and Respondent's due process rights. Resp't Mot. at 3. It further preserves the following issues for judicial review: "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." *Id.* The Commission has already affirmed this Court's denial of Respondent's motion to disqualify based on asserted removal protections. *See* Order Aff'g Admin. L. Judge's Denial of Mot. to

Complaint Counsel opposes the motion based on the following contentions: (1) this Court already ruled that the regulation defining "defect," rather than the common law definition, controls, and there are genuine issues of material fact concerning the existence of defect under that definition; (2) Respondent's arguments regarding causation and the definition of substantial risk of injury are not legally supported; and (3) Respondent's Constitutional arguments are misplaced or not properly raised in this forum. *See* Compl. Counsel's Resp. in Opp'n to Leachco, Inc.'s Mot. for Summ. Decision & Supporting Memo., at 1–2 (June 23, 2023) ("Compl. Counsel Opp'n").

This Court held oral arguments on both motions on June 29, 2023. An oral ruling was made immediately following those arguments, and the parties requested this Court provide that ruling in writing. For the reasons set forth below, this Court denies both parties' motions.

I. Complaint Counsel Is Not Entitled to Summary Decision Regarding Reasonably Foreseeable Misuse of the Podster or Whether an Alleged Defect Creates a Substantial Risk of Injury.

A. There are genuine issues of material fact regarding whether a defect in the Podster creates a substantial risk of injury.

Complaint Counsel did not move for summary decision regarding whether a defect exists; it asserts there are no genuine issues of material fact regarding another element of its claim—substantial risk of injury. *See* Compl. Counsel Mot. at 2. Respondent argues this Court cannot reach a conclusion on a substantial risk of injury if it cannot also assess the predicate—the existence of a defect. Resp't Opp'n at 1. This Court need not rule on that issue, as there are genuine issues of material fact regarding the risk of injury itself.

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) (2023). Complaint Counsel states that Commission regulations allow "substantial risk of injury" to be demonstrated by *either* seriousness or likelihood of injury. *See* Compl. Counsel Mot. at 22; 16 C.F.R. § 1115.12(g)(1)(ii) (2023) ("Even one defective product can present a substantial risk of injury and provide a basis for substantial product hazard determination under section 15 of the CPSA if the injury which might occur is serious and/or if the injury is likely to occur."); *see also* 16 C.F.R. § 1115.12(g)(1)(iii) ("A risk is severe if the injury which might occur is serious and/or if the injury is likely to occur.").[2]

Disqualify, CPSC Docket No. 22-1 (Oct. 7, 2022). This Court does not rule on these issues here, but Respondent made proper and timely appeal, so they have been preserved for review by the Commission and/or any reviewing court. *See Nelson v. Adams USA, Inc.*, 529 U.S. 460, 469 (2000) (requiring that the "lower court be fairly put on notice as to the substance of the issue" to preserve the issue for review).

[2] This Court notes that while Complaint Counsel cited subsection (iii) in its motion for partial summary decision, it did cite subsection (ii)—arguably more relevant to the definition of "substantial risk of injury," specifically—in its opposition. *See* Compl. Counsel Opp'n at 23.

Respondent asserts the ordinary meaning of the statutory text precludes Complaint Counsel's interpretation and claim, arguing that the language requires a "significantly high likelihood of injury," and that severity of injury alone cannot justify a finding of substantial risk of injury. *See* Resp't Opp'n at 6–8; Resp't Mot. at 38. Respondent further asserts Complaint Counsel cannot rely on interpretive regulations in its action, and that the cited regulatory provisions do not apply to the claim alleged. Resp't Opp'n at 8 n.1.

Respondent is incorrect that the regulations may not apply to this claim. While Part 1115 does regard reporting requirements, the purpose is to "indicate the actions and sanctions which the Commission may require or impose to protect the public from substantial product hazards, as that term is defined in section 15(a) of the CPSA." 16 C.F.R. § 1115.1. Subsection 12(g) involves evaluation of the substantial risk of injury associated with a substantial product hazard.[3]

This is therefore the Commission's promulgated metric for evaluating a substantial risk of injury as it relates to a substantial product hazard under section 2064(a)(2), and it is not facially unreasonable in the abstract. And Respondent has not alleged that this regulation is an unreasonable interpretation of the statute, so this Court thus need not rule at this stage on the applicability of subsection 12(g)(1)(ii) or evaluate Respondent's asserted interpretation of the statutory text as requiring a "significantly high likelihood."

Complaint Counsel has provided evidence of three infant deaths associated with use of the Podster. It correctly notes that the likelihood of injury is based on the number of injuries reported, the intended or reasonably foreseeable product use or misuse, and the population exposed, 16 C.F.R. § 1115.12(g)(1)(iii), but subsection (ii) allows evaluation of a substantial risk of injury based on seriousness of injury—in this case death, *see id.* § 1115.12(g)(1)(ii).

Respondent's contention regarding the number of alleged deaths in comparison to the number of products sold could have merit regarding likelihood. And Complaint Counsel could demonstrate that the design or misuse of the Podster could lead to infant deaths, posing a substantial risk of based on the severity of the injury. But the facts presented do not preclude a genuine issue of material fact regarding either metric. As this Court has recognized that Commission regulations allow evaluation based on the gravity, Complaint Counsel is still required to demonstrate the alleged defect's creation of that risk.

Complaint Counsel has provided expert testimony regarding evaluation of the three incidents and the possible causes based on the product design and reasonably foreseeable use. Expert testimony is a good shield from summary decision, but a bad sword. Such proffered evidence precludes summary decision in favor of Respondent regarding either a defect or substantial risk of injury, *see infra* Section II, but it does not negate any question of fact. The issue may be amplified at hearing, but this Court cannot infer qualifications and findings, and it

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Even so, this Court acknowledges subsection (ii) as contemplating seriousness *or* likelihood in analyzing a substantial risk of injury.

[3] This analysis also applies to Respondent's assertion that section 1115.4 similarly does not apply to the claim. *See* Section II.A., *infra*.

cannot credit facts in dispute where Respondent has not had the opportunity to cross-examine the experts.

The expert testimony includes a conclusion that the Podster "[c]auses a flexed head/neck and flexed trunk posture during supine lying, inhibiting normal breathing." Compl. Counsel Opp'n at 10 (citing Ruff Decl., Ex. 9 at 5–6). The remainder of the findings cited by Complaint Counsel seem to result from a lack of supervision that results in an infant moving into a position to suffocate on the product material—a situation against which Respondent has admittedly warned, and thus is the basis of its contention that Complaint Counsel has not brought a defective warning claim.

Even if this Court were to find that a claim based on inadequate warning was precluded at this stage, it could not dispose entirely of a triable question concerning foreseeable misuse where proffered evidence demonstrates an alleged design defect that results in the alleged harm—possible suffocation. But this Court does not find that consideration of reasonably foreseeable misuse is only applicable to a warning defect claim, and it therefore does not reach Respondent's question of whether it is inappropriate for Complaint Counsel to assert such a claim post-discovery.

B. There are genuine issues of material fact regarding reasonably foreseeable misuse.

Reasonably foreseeable misuse is a factor on which Complaint Counsel may base its defective product claim against the Podster. *See* 16 C.F.R. § 1115.4 ("In determining whether the risk of injury associated with a product is the type of risk which will *render the product defective*, the Commission and staff will consider, as appropriate: . . . the *role of consumer misuse of the product and the foreseeability of such misuse*.") (emphasis added).[4] This conclusion is also supported by the inclusion of factors unrelated to reasonably foreseeable misuse in the listed considerations for product defect.

The Commission has provided eleven factors for evaluating whether the risk of injury associated with a product is the type that renders a product defective:

> The utility of the product involved; the nature of the risk of injury which the product presents; the necessity of 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;

[4] It is arguably improper for Complaint Counsel to cite subsection (d), as it relates to and example where a product "is not accompanied by adequate instructions and safety warnings." 16 C.F.R. § 1115.4(d). That subsection does, however, go on to say: "Reasonably foreseeable consumer use or misuse, *based in part* on the lack of adequate instructions and safety warnings, could result in injury." *Id.* (emphasis added). That language implies that reasonably foreseeable misuse, *based in part* on something other than inadequate warning—e.g., the product's design itself—could result in injury.

> 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.

Id. The language immediately before these considerations provides that "not all products which present a risk of injury are defective," and the language after directs that if the information reasonably supports that a defect exists, one should evaluate whether it creates a substantial product hazard [utilizing the assessment factors in section 1115.12(f)]. *Id.*

The preceding and proceeding language demonstrates no explicit tie to warning defects, specifically. Further, multiple factors listed do not regard inadequate warning—e.g., utility, nature of risk, necessity, population exposed, and obviousness. Consumer misuse is listed after the adequacy of warnings, but the text reveals no apparent relation. The adequacy of warnings refers to the prior factor—i.e., obviousness of risk, and the adequacy of warnings "to mitigate such risk." But the portion on consumer misuse only references the role of misuse and the foreseeability of such misuse, not the foreseeability of misuse in the face of inadequate warning.

Respondent is therefore incorrect in asserting that foreseeable misuse is immaterial to the Commission's allegations. *See* Resp't Opp'n at 12–16 (arguing that the Commission is "foreclosed from relying on foreseeable misuse" to establish a defect because Complaint Counsel has not alleged a defective warning claim and cannot establish a design defect). Even so, Complaint Counsel is not entitled to summary decision on reasonably foreseeable misuse based solely on the conclusions of its proffered experts.

As noted above, Complaint Counsel has provided expert reports demonstrating the likelihood of consumer misuse based on human behavior and product advertising. *See* Compl. Counsel Mot. at 14–18.[5] This Court disagrees with Respondent's characterization of the proffered expert testimony as "conclusory" or "speculative." *See* Resp't Opp'n at 9. The cases cited preclude expert testimony at this stage where it is merely "conclusory assertions about ultimate legal issues." *Id.*; *Hayes v. Douglas Dynamics, Inc.*, 8 F.3d 88, 92 (1st Cir. 1993).[6]

Complaint Counsel's expert reports do not simply state legal conclusions—e.g., the Podster has a defect or creates a substantial risk of injury. Expert conclusions in support of those legal elements include findings that the product may cause suffocation based on its properties, or that an infant may roll if unsupervised. Nevertheless, there is still material dispute about those

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[5] Complaint Counsel *also* asserts the Podster's warnings are inadequate. *See id.* at 18–21. Respondent asserts this is not a defective warning case, contending that Complaint Counsel has repeatedly stated it is not, and that it "tardily" attempted to introduce evidence regarding deficient product warnings in a supplemental response to an interrogatory after close of discovery. Resp't Opp'n at 14; Resp't Mot. at 26–28. This Court need not rule on this assertion at this stage, as it is sufficient for Complaint Counsel to survive a summary decision motion that evidence of reasonably foreseeable misuse is relevant to the existence of a defect under Commission regulations.

[6] *Major League Baseball Properties Inc. v. Salvino Inc.* similarly involved a lack of proffered *factual support* for main contentions. 542 F.3d 290, 318–19 (2d Cir. 2008).

facts because, as noted above, such expert testimony precludes summary decision against Complaint Counsel but does not support summary decision in its favor.

II. Respondent Is Not Entitled to Summary Decision Regarding the Existence of a Defect and Whether That Defect Creates a Substantial Risk of Injury.

A. There are genuine issues of material fact regarding whether a defect exists.

The Commission defines "defect" in its regulation governing when a firm must report:

> In determining whether it has obtained information which reasonably supports the conclusion that its consumer product contains a defect, a subject firm may be guided by the *criteria the Commission and staff use in determining whether a defect exists*. At a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function.

16 C.F.R. § 1115.4 (emphasis added).[7] Respondent asserts this definition does not apply to the present claim because the provision regards reporting. As with the applicability of section 1115.12(g)(1), *see* Section I.A., *supra*, this Court finds this definition applicable, as it was officially promulgated and provides the Commission's considerations for evaluating the existence of a defect.

Respondent further asserts the term must be defined by ordinary or common law meaning—i.e., a manufacturing, design, or warning defect. *See* Resp't Mot. at 24–26. In that vein, it states that Complaint Counsel does not allege a manufacturing or warning defect. *See id.* at 26–29. It then claims Complaint Counsel cannot demonstrate a design defect, and that Complaint Counsel improperly equates reasonably foreseeable misuse with a defect. *See id.* at 29–32. This Court already found that reasonably foreseeable misuse is a *consideration* in determining whether a defect exists. *See* Section I.B., *supra*.

This Court does not recognize a dispute between the Commission's regulation and the common law. The provided definition is informed by products liability common law requirements and in fact includes the three defect categories, one of which Respondent asserts

[7] Complaint Counsel incorrectly asserts this Court already ruled that regulatory definition of "defect" controls in this proceeding. Compl. Counsel Opp'n at 14–17. As Respondent correctly noted during oral argument, this Court's prior order only stated that "the full scope of the definition advanced by the CPSC should be recognized at this stage [preliminary action] for the purposes of discovery." Order Denying Leachco, Inc.'s Mot. for Protective Order & Granting Compl. Counsel's Mot. to Compel Prod. of Elec. Commc'ns Pursuant to Compl. Counsel's 2d Set of Reqs. for Prod. of Docs. to Resp't, at 8 n.2 (Dec. 16, 2022). This Court went on to state, "The CPSC has in fact provided a definition, and absent some argument or authority suggesting why the definition is unreasonable, I will permit it as a basis for reasonable injury." *Id.* This Court nevertheless *now* finds it to be a reasonable interpretation of the regulation for the purposes of surviving summary decision and for use going forward.

Complaint Counsel needs to demonstrate for its claim. The provision includes a manufacturing defect. *See* 16 C.F.R. § 1115.4 ("A defect, for example, may be the result of a manufacturing or production error; that is, the consumer product as manufactured is not in the form intended by, or fails to perform in accordance with, its design."). It also includes a design defect:

> [T]he design of and the materials used in a consumer product may also result in a defect. Thus, a product may contain a defect even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public. A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended.

Id. It finally includes a warning defect:

> A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions. With respect to instructions, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury.

Id.

Having already declined to rule on the appropriateness of Complaint Counsel's supplemental response regarding the allegation of a warning defect, and finding that the regulation does not tie foreseeable misuse only to an inadequate warning claim, this Court addresses only whether Complaint Counsel has alleged facts allowing the reasonable conclusion that the Podster is defective.

Respondent contends, "[T]he Commission has not alleged and does not argue that the Podster, when it left Leachco's hands, was unreasonably dangerous for its *intended* use. To the contrary, the whole premise of the Commission's action is that Podster is too dangerous for its *unintended* misuse." Resp't Opp'n at 15 (citing *Hunter v. Shanghai Huangzhou Elec. Appliance Mfg. Co.*, 505 F. Supp. 3d 137, 152–53 (N.D.N.Y. 2020) (requiring comparison of a product's utility against its inherent danger)).

But that is too narrow a reading of the regulation. The regulation states that a "design defect may *also* be present" based on the "failure of the product to operate as intended. 16 C.F.R. § 1115.4 (emphasis added). The sentence before does not require an evaluation of intended use, stating only that a defect may exist if the design presents a risk of injury, period. *Id.* Complaint Counsel therefore need not provide facts specifically demonstrating an evaluation of the product's utility versus the alleged risk to survive summary decision.

Respondent further claims that cases cited by Complaint Counsel support its own argument that the Commission must evaluate utility and reasonable alternative design. *See* Resp't Opp'n at 15, 15 n.3 (citing *Southland Mower Co. v. CPSC*, 619 F.2d 499 (5th Cir. 1980); *Aqua Slide 'N' Dive Corp. v. CPSC*, 569 F.2d 831, 839 (5th Cir. 1978)); *see also* Compl. Counsel Mot. at 13. While this Court agrees that Complaint Counsel's assertion that it is entitled

to assess foreseeable misuse in determining the existence of a defect is wholly supported by only its citation to *Zen Magnets v. CPSC*, No. 17-cv-02645-RBJ, 2018 WL 2938326, at *7 (D. Colo. June 12, 2018), rather than to *Southland Mower Co.* or *Aqua Slide*, those cases still do not support Respondent's contention.

Both cases involved challenges to promulgated safety standards for specific products and refer to a different statutory provision governing such promulgation that requires findings regarding "the probable effect of such rule upon the utility, cost, or availability of such products to meet such a need." 15 U.S.C. § 2058(f)(1)(C); *Southland Mower Co.*, 619 F.2d at 514; *Aqua Slide*, 569 F.2d at 839–40. The provision at issue here does not require such a finding, because the Commission is not seeking to promulgate a safety standard.

In the context of the instant litigation, utility is simply one consideration in determining whether a defect exists. Complaint Counsel has proffered evidence and testimony regarding the nature of the risk, the population exposed, the obviousness of the risk, warning adequacy, foreseeability of misuse, as well as the Commission's own expertise and investigative methods. Respondent obviously does not dispute some utility in its own product, but Complaint Counsel need not make findings specifically regarding the product's level of utility for evaluation against the alleged risk to survive summary decision on the existence of a defect.

B. There are genuine issues of material fact regarding whether the alleged defect creates a substantial risk of injury.

This Court already found that Complaint Counsel is not entitled to summary decision on this question. *See* Section I.A., *supra*. Respondent is not entitled for the same reasons. Complaint Counsel may rely on the severity of alleged injury alone. It must nevertheless still demonstrate that that injury is the result of the alleged defect.

Complaint Counsel proffered expert testimony regarding the effect of the Podster design on infant breathing in the supine position, as well as the risk of injury from a lack of supervision—an alleged reasonably foreseeable misuse. This is sufficient to survive summary decision on the substantial risk of injury.

III. Conclusion

Complaint Counsel's motion for partial summary decision is **DENIED**.

Respondent's motion for summary decision is **DENIED**.

Michael G. Young
Administrative Law Judge

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