FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION
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August 2, 2023

In the Matter of

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

Respondent.

ORDER GRANTING IN PART AND DENYING IN PART RESPONDENT'S MOTION TO EXCLUDE THE EXPERT TESTIMONY PROFFERED BY THE CONSUMER PRODUCT SAFETY COMMISSION

Respondent moved to exclude the following expert testimony:

I. Testimony of Dr. Mannen, Dr. Katwa, and Ms. Kish to the extent factual information relied upon was not disclosed during fact discovery.
II. Testimony of Dr. Katwa and Ms. Kish on allegedly defective warnings because they are unhelpful and irrelevant.
III. Dr. Mannen's testimony because of failure to disclose information underlying her report, and because it is unreliable and irrelevant.
IV. Dr. Katwa's testimony on matters outside his proffered expertise.
V. Dr. Katwa's and Ms. Kish's attempts to introduce fact testimony through expert reports.

Leachco, Inc.'s Mot. to Exclude the Expert Test. Proffered by the Consumer Prod. Safety Comm'n, at 1 (July 14, 2023).[1]

Complaint Counsel opposes the motion, asserting its expert testimony is reliable and relevant, and "Leachco's generalized and unspecific claims must be raised on cross examination and not by excluding evidence." Compl. Counsel's Opp'n to Leachco's Mot. in Lim. & *Daubert* Mot., at 2 (July 24, 2023).

For the following reasons, this Court GRANTS Respondent's motion with regard to testimony about allegedly defective warnings, testimony outside of Dr. Katwa's proffered expertise, and fact testimony outside the scope of personal knowledge. It DENIES Respondent's

[1] This Court acknowledges the following reservation by Respondent: "Leachco reserves the right to supplement and/or renew this motion—or to address these matters in its post-hearing brief—once it has had the opportunity to cross-examine the Commission's proffered expert witness." *Id.*

motion with regard to alleged unreliability or irrelevance, as well as to factual information relied upon by the proffered experts.

I. Complaint Counsel Should Have Provided the Facts or Tested Materials During Fact Discovery, But Exclusion Is Too Extreme a Sanction Here Because of the Time Respondent Was Aware of the Deficiency and Failed to Act.

Respondent provided significant support for excluding facts, or testimony based on facts, not disclosed during fact discovery. Mem. in Supp. of Leachco, Inc.'s Mot. to Exclude the Expert Test. Proffered by the Consumer Prod. Safety Comm'n, at 6–8 (July 14, 2023); *see Zurich Am. Ins. Co. v. Hardin*, No. 8:14-CV-775-T-23AAS, 2020 WL 1150981 (M.D. Fla. Mar. 10, 2020); *R.D. v. Shohola, Inc.*, No. 3:16-CV-01056, 2019 WL 6211243 (M.D. Pa. Nov. 20, 2019); *Brown v. Wal-Mart Store, Inc.*, No. 09-CV-02229-EJD, 2018 WL 2011935 (N.D. Cal. Apr. 27, 2018); *N.J. Physicians United Reciprocal Exch. v. Boynton & Boynton, Inc.*, No. 12-5610 (PGS), 2017 WL 3624239 (D.N.J. Aug. 23, 2017); *ParkerVision, Inc. v. Qualcomm Inc.*, No. 3:11-cv-719-J-37-TEM, 2013 WL 3771226 (M.D. Fla. July 17, 2013); *Henry v. Quicken Loans, Inc.*, No. 04-40346, 2008 WL 4735228 (E.D. Mich. Oct. 15, 2008); *Bizrocket.com, Inc. v. Interland, Inc.*, No. 04-60706-CIV, 2005 WL 6745904, at *1 (S.D. Fla. Aug. 24, 2005).

These cases generally acknowledged, however, that exclusion should be a last resort. *See Shohola, Inc.*, 2019 WL 6211243, at *2 (quoting *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1977)) ("[T]he exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence."); *N.J. Physicians*, 2017 WL 3624239, at *13 ("Under these circumstances [no bad faith or willfulness] . . . the Court finds that striking the [reports] in total is too harsh a sanction to impose.").[2] Even *Hardin*, which Respondent cites significantly and is generally supported of its position, only precluded the offending party from introducing the withheld document and having the expert offer specific opinions based on that withholding. 2020 WL 1150981, at *3.

Fact discovery closed on March 20, 2023, and expert disclosures were due by April 28, 2023. Order on Prehearing Schedule, at 1 (Sept. 16, 2022). This Court agrees with the provided authority that facts on which experts rely should have been disclosed by the March deadline.[3]

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[2] It should be noted that Respondent's statement in the explanatory parenthetical accompanying *N.J. Physicians* is too strong for what the case actually states. Respondent wrote, "striking plaintiff's expert report containing information not disclosed during fact discovery." Mem. at 7. The court did not strike the report; it precluded reliance on the undisclosed information in the report, and it ordered another without the offending information because there was sufficient time remaining before trial. 2017 WL 3624239, at *13.

[3] Complaint Counsel asserted the Commission's Rules contemplate the expert disclosure deadline is the actual close of discovery. Opp'n at 3–4. This is an unreasonable reading of the regulation, however, in the face of significant case law to the contrary. Just because the "facts known [by the expert]" and the "substance of facts and opinions to which the expert is expected to testify" must be provided in the expert testimony, 16 C.F.R. § 1025.31(c)(4)(i)(A) (2023), that

As noted in this Court's order allowing Complaint Counsel's expert witness hearing testimony, Respondent had the expert reports since April 28. Order Granting Compl. Counsel's Mot. for Leave to Amplify Written Direct Expert Test., at 1 (Aug. 1, 2023). Similar to Respondent's noted failure to move for further discovery based on late-noticed likely inclusion of a witness, *see* Order Granting Leachco, Inc.'s Mot. to Strike Konica McMullen from the Comm'n's Witness List, at 3 (July 28, 2023) (noting that Respondent was aware of the likelihood the witness would be called since May), it had not made any such request after receiving the report in April, with sufficient time available to request a revised report or to have the underlying facts or materials provided. *See N.J. Physicians*, 2017 WL 3624239, at *13.

In the same way that Complaint Counsel should not withhold the factual information it possesses, and will not be able to present evidence of a claim it consistently denied bringing, *see* Section II, *infra*, Respondent cannot wait two months until the eve of hearing to demand the exclusion of all of Complaint Counsel's proffered testimony on the basis that evidence was improperly withheld. The expert reports are not excluded, with some caveats, *see* Sections IV, V, *infra*, and cross-examination is the proper mechanism for challenging the witnesses and the evidence upon which they relied. *See Hearts with Haiti, Inc. v. Kendrick*, No. 2:13-CV-00039-JAW, 2014 WL 4773479, at *5 n.5 (D. Me. Sept. 24, 2014); *Fish Farms P'Ship v. Winston-Weaver Co.*, No. 2:09-CV-163, 2012 WL 12965440, at *1 (E.D. Tenn. Oct. 23, 2012).

II. Complaint Counsel Did Not Allege a Warning Defect and Is Precluded from Presenting Evidence Regarding Inadequate Warnings Based on Its Claimed Irrelevance Throughout Discovery.

Complaint Counsel has consistently claimed it is not bringing a warning-defect claim. Its objections to requested discovery reflect this. *See*, *e.g.*, Mot. at 11 (citing Appx. of Exs. to Leachco's Prehr'g Mots. Submitted for In-Camera Rev., Ex. 6, at 16–17 (July 14, 2023)). Its response to an interrogatory regarding warning adequacy included contentions that such a request is "not reasonably calculated to lead to the discovery of admissible evidence *pertaining to the issue*," and that the issue is "not whether the product with modified warnings or instructions would pose a hazard." Appx. Ex. 6, at 16 (emphasis added).

Its first supplemental response reaffirmed that it "is not making contentions about any 'warning or instruction' Leachco 'provided improperly or failed to provide in connection with the Podster." *Id.* at 17. Finally, its fourth supplemental response stated, "[I]nformation regarding the insufficiency of the Podster's warnings is contained within, or can be derived from, the expert testimony." *Id.*

Complaint Counsel therefore now explains that evidence of warning inadequacy is a consideration in whether a defect exists, under Section 1115.4. Opp'n at 13–14. While true,[4]

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does not mean Complaint Counsel does not have to produce those facts on hand during fact discovery.

[4] *See* 16 C.F.R. § 1115.4 ("In determining whether the risk of injury associated with a product is they type of risk which will render the product defective, the Commission and staff will consider, as appropriate: . . . the adequacy of warnings and instructions to mitigate such risk . . . .").

Complaint Counsel consistently objected to the relevance of discovery regarding the adequacy of the Podster's warnings, claiming it was not brining a warning-defect claim. Now it uses its expert testimony and supplemental discovery responses to assert warning adequacy is relevant to its design-defect claim. If it is relevant to its design-defect claim now, it was relevant then. [5]

Respondent cited significant authority to assert evidence of a claim not alleged should be excluded because it cannot assist this Court's analysis. Mot. at 10; *see*, *e.g.*, *Kempner Mobile Elecs., Inc. v. Sw. Bell Mobile Sys.*, 428 F.3d 706, 713 (7th Cir. 2005); *United States v. Cantrell*, 999 F.2d 1290, 1292 (8th Cir. 1993); *Grayson v. No Labels, Inc.*, 601 F. Supp. 3d 1251 (M.D. Fla. 2022). Complaint Counsel responds that parties may be put on notice through mention of issues in depositions, other filings, or the opposing party's own expert testimony. Opp'n at 16–18. Complaint Counsel's cited authority is distinguishable, however.

The court in *Ramirez v. OMBS Sec. Sys. LLC* cited *Connelly v. General Medical Corp.* to find no unfair surprise where the issue was raised during multiple depositions. No. 19-20216, 2021 WL 4992569, at *2 (S.D. Fla. Aug. 20, 2021). *Connelly*, however, specified that "additional facts" *about a known theory* were not precluded—not a new theory of liability. 880 F. Supp. 1100, 1110 (E.D. Va. 1995) (emphasis added); *see id.* ("The Court can easily stir these new allegations [facts] into the analytical brew of this case and still apply the same controlling legal principles."). *Citizens Federal Bank, FSB v. United States* similarly noted that plaintiffs previously inappropriately "attempted to raise a new damages theory" that was a "totally *new and as-yet-explored* area of recovery." 59 Fed. Cl. 507, 513 (2004) (emphasis added). Finally, the decision not to preclude evidence in *Martin v. J.A.M. Distributors Co.* relied on the opposing party having sufficient time to depose because it was offered "before the end of the applicable discovery period." No. 1:08-CV-298, 2009 WL 10677609, at *2 (E.D. Tex. Apr. 9, 2009).

Any supplement at time of or after expert disclosures is different than the ruling above regarding late- or unproduced discovery materials. There, Respondent's awareness of the likely witnesses and ability to request reopening of discovery was based on its knowledge of the claim—design defect—for which it had been preparing since, at least, Complaint Counsel's first declaration that it was not pursuing a warning-defect claim.

Complaint Counsel's proffered expert testimony and supplemental responses regarding a warning defect introduced an entirely new claim. The other instances did not prejudice Respondent because this Court finds that it likely could have cured its inadequate discovery in the remaining time. But a change to the alleged claim prejudices Respondent, particularly where Complaint Counsel has consistently stated it is not bringing such a claim, and where it has consistently objected to discovery based on irrelevancy of such associated information.

Most importantly, as this Court understands the theory and proffered evidence, there does not appear to be a defect in warning because Complaint Counsel seems to acknowledge that the reasonably foreseeable misuse alleged cannot be mitigated by *any* warnings Respondent could

[5] Given that its experts were clearly evaluating the adequacy of the warnings, Complaint Counsel should have at least supplemented its responses prior to expert disclosure to withdraw its objection to relevance, after consultation with its experts, even if it could not yet answer in full.

provide. The Complaint itself acknowledges that the Podster contains warnings not to use it for sleep, while unsupervised, or in conjunction with other surfaces or materials. *See* Compl. ¶¶ 15–16; *see also id.* ¶¶ 17–19 (regarding warnings about infant size, positioning, and use in contravention to provided warnings).

The extent to which the Product may be found to contain a defect, sufficient to create a substantial product hazard, will be based on reasonably foreseeable misuse, not because the warnings are inadequate. See, e.g., Compl. ¶ 20 ("*Despite the warnings and instructions*, it is foreseeable that caregivers will use the Podster without supervision. It is also foreseeable that caregivers will use the Podster for infant sleep.") (emphasis added); ¶ 38. Complaint Counsel has staked itself to what this case is about, and this Court informed both parties that they are going to stick to that theory. Testimony and evidence regarding adequacy of the Podster's warnings is therefore excluded.

III. Pending Cross-Examination, Respondent Has Not Demonstrated That Dr. Mannen's Testimony Is Unreliable or Irrelevant.

Respondent cites *Daubert* regarding the Court's "gatekeeping" function to ensure expert testimony is reliable and relevant. Mot. at 3 (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). but the motion is not really a *Daubert* motion. While it claims Dr. Mannen's testimony should be excluded because it neither "rests on a reliable foundation," nor is "relevant to the task at hand," *id.* at 11, Respondent's argument mainly rests on either Complaint Counsel's failure to disclose data underlying the report or its reliance on anecdotal information, *id.* at 12, 14.

This Court has already dealt with the failure to disclose, or late disclosure of, facts or material relied upon by Complaint Counsel's experts. *See* Section I, *supra*. Further, this Court already found that Dr. Mannen's testimony is relevant to the action. *See* Order Denying Compl. Counsel's Mot. for Partial Summ. Dec. & Denying Resp't's Mot. for Summ. Dec., at 4 (citing Compl. Counsel's Resp. in Opp'n to Leachco, Inc.'s Mot. for Summ. Dec. & Supporting Mem., at 10–11 (June 23, 2023). The only challenge presented by Respondent is therefore to the allegedly anecdotal information on which Dr. Mannen partially relied.

Respondent's cited cases do generally support the contention that anecdotal evidence is "one of the least reliable sources to justify opinions about both general and individual *causation*." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (emphasis added); *see* Mot. at 11. *See also Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 380–81 (5th Cir. 2010); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995). It should be noted that McCain decried such sources in evaluation of *causation*, not risk. *In re Diet Drugs*, *see* Mot. at 14, is even more instructive in this regard.

In re Diet Drugs supports that a party cannot rely on anecdotal reports for causation. No. MDL 1203, 2001 WL 454586, at *15 (E.D. Pa. Feb. 1, 2001) (citing *Hollander v. Sandoz Pharms., Inc.*, 95 F. Supp. 2d 1230, 1237 (11th Cir. 1999)). The court precluded the testimony because the expert had not adequately explained how or why he could reliably extrapolate the results from a rat study to humans. *Id.* It referred to the study, relied upon by the FDA, and

noted that the "FDA primarily engages in a process of risk assessment rather than determining causation, and the relevance to causation of evidence used to assess risk is not clear." *Id.* Additionally, the court found the analysis failed to account for the "presence of confounding factors such as age, diet, stress, and other causes." *Id.* at *13.

The present action similarly does not require causation, with respect to the expert testimony proffered. Causation is a part of the claim—whether a defect exists which *causes* a substantial risk of injury. But the expert testimony addresses the Commission's risk assessment: the risk that the Podster will be foreseeably misused, and the risk that misuse will result in serious injury. Also, the reports here seem to recognize confounding factors—e.g., in a crib, unsupervised, presence of another object, etc.

Dr. Mannen's testimony is relevant to the risks associated with foreseeable misuse of the product. Complaint Counsel has provided sufficient information regarding her expertise in this field. And Respondent has not challenged that expertise. Dr. Mannen's testimony is therefore not excluded.

IV. Dr. Katwa Has Only Been Demonstrated to Possess Expertise as a Pediatric Pulmonologist and Sleep Specialist, So Any Conclusions Regarding the Podster's Design or Likely Caregiver Habits Must be Established by Experts in Such Fields Before Dr. Katwa May Refer to Such Conclusions.

An expert witness must be competent in the subject matter to which he or she will testify. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999); *Daubert*, 508 U.S. at 592; *Tanner v. Westbrook*, 174 F.3d 542, 548 (5th Cir. 1999); *Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 615 (7th Cir. 1993); *Bryant v. 3M Co.*, 78 F. Supp. 3d 626, 632 (S.D. Miss. 2015); *see also* Mot. at 15–16.

Respondent correctly asserts that Dr. Katwa is a pulmonologist specializing in "evaluation and treatment of infants and children with sleep apnea and other sleep and breathing disorders." Mot. at 16. He is therefore not able to appropriately testify as an expert to the following challenged topics:

- Whether the Podster "acts like" an inclined sleeper. Mot. at 16 (quoting Appx. Ex. 1, at 17).
- Whether the Podster "facilitates flexion on the head and trunk of infants." *Id.* at 16 (quoting Appx. Ex. 1, at 17).
- Whether an infant is "likely to get entrapped" if it rolls. *Id.* at 16–17 (quoting Appx. Ex. 1, at 17).
- "[M]arketing disinformation." *Id.* at 17 (quoting Appx. Ex. 1, at 29–30).

Complaint Counsel makes several references to Dr. Katwa's experience treating "thousands" of patients—infants and children—each year. Opp'n at 22, 24. This, it claims, provides him expertise regarding "certain areas of consumer behavior and infant movement." *Id.* at 22. This Court finds this insufficient. Dr. Katwa is not a competent expert regarding consumer misuse or even the position in which a Podster maintains an infant. Complaint

Counsel has other experts to speak to that. Similarly, he may be competent to testify about safe sleeping surfaces, and while he might conclude simply that the Podster is not a flat surface—e.g., not safe for sleeping—he is not competent to conclude that the Podster "acts like" another CPSC-regulated product.

Complaint Counsel appropriately argues that an expert may "rely on opinions of experts in areas outside [their] own field of expertise." Opp'n at 24 (citing *Dura Automotive Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614–15 (7th Cir. 2002)). But *Dura* also acknowledged that the expert was not qualified to opine on the first of two issues, and that the first issue was needed to even get to the issue that involved the expert's expertise. 285 F.3d at 615 ("[W]ithout an expert opinion on [the first] issue Dura could not get to the second and so could not prevail.").

It follows then that Dr. Katwa can only testify as to the risk of hypoxemia, "hypoxia, low heart rate, reduced blood flow to the body particularly the brain, loss of consciousness, cardiorespiratory arrest and eventually death," Opp'n at 23 (quoting CCX-3, at 30), after competent experts testify to the foreseeability that a consumer will allow an infant to sleep in the Podster or leave it unsupervised, and that that misuse will allow an infant to reach a body position that causes such risks.

As this Court has acknowledged that Dr. Mannen and Ms. Kish are competent to testify about such things, Dr. Katwa's testimony regarding the Podster itself or the marketing, what it facilitates, or likely risks from a lack of supervision will not be helpful to this Court's evaluation. He is only competent to testify to the risks associated with the body positioning on or off the pillow that results from foreseeable misuse. The challenged portions of Dr. Katwa's testimony are therefore excluded.

V. Complaint Counsel's Expert Witnesses May Not Testify to Establish Facts About the Incidents to Which They Were Not Present Unless Such Conclusions Have Been Admitted into Evidence.

Respondent claims the expert testimony attempts to "resolve factual 'conflict'" by making statements of fact based on the witness reports in the In-Depth Investigation Reports ("IDI"), particularly where the expert report acknowledges that there is a "conflicting report of the infant's sleeping position." Mot. at 18 (citing Appx. Ex. 1, at 26). Complaint Counsel responds that it is proper for its expert witnesses to summarize the Podster IDIs, claiming that they are reviewing official reports and applying expertise rather than making up facts. Opp'n at 27 (citing *United States v. DeSimone*, 488 F.3d 561, 576–77 (1st Cir. 2007)).

The court in *Stephens v. Union Pacific R.R. Co.*, cited by Respondent, Mot. at 18, held that because there was no testimony regarding plaintiff's harmful exposure, experts had no basis to testify to the degree of exposure supporting their findings. 935 F.3d 852, 857 (9th Cir. 2019). Complaint Counsel claims the case is inapposite because there is no evidentiary gap here. Opp'n at 28. But that assertion is based on the contention that the IDIs are "reliable, as they are official,

legally-authorized public records of CPSC Field staff investigations that include official records and witness statements." *Id.*[6]

This Court, however, has found that the IDIs are not covered by the public record exception to hearsay. *See* Order Deferring Dec. on Compl. Counsel's Mot. in Lim. & Mem. in Supp. to Admit In-Depth Investigation Reps., at 3–4 (Aug. 2, 2023). Until such time as a foundation is established for use or admission of the IDIs at hearing, *see id.* at 4, Complaint Counsel experts' factual assertions about the incidents are excluded.

VI. Conclusion

Respondent's motion to exclude the testimony of Dr. Mannen, Dr. Katwa, and Ms. Kish based on facts not disclosed during fact discovery is **DENIED**, to the extent that they are competent to testify.

Respondent's motion to exclude the testimony of Dr. Katwa and Ms. Kish on allegedly defective warnings is **GRANTED**.

Respondent's motion to exclude Dr. Mannen's testimony as unreliable or irrelevant is **DENIED**.

Respondent's motion to exclude Dr. Katwa's testimony on the challenged matters outside of his expertise is **GRANTED**.

Respondent's motion to exclude Dr. Katwa's and Ms. Kish's testimony that states reported IDI information as fact is **GRANTED**. This Court will reconsider based on the establishment of a foundation for the IDIs.

Michael G. Young
Administrative Law Judge

Distribution:

[6] Complaint Counsel is also incorrect to rely on *DeSimone*. There, the court admitted a summary chart *only* because everything listed in it had already been admitted in evidence. 488 F.3d at 577 (citing *United States v. Marchini*, 797 F.2d 759, 765–66 (9th Cir. 1986)) ("The listed information was, as conceded by the defense, data already admitted into evidence, hence no problem arose under the Rule's limitations concerning "otherwise inadmissible" evidence.").

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