UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

COMPLAINT COUNSEL'S OPPOSITION TO
LEACHCO'S MOTION *IN LIMINE* AND *DAUBERT* MOTION

Respondent Leachco, Inc. submitted two motions on July 14, 2023:

(1) a motion *in limine* to exclude: (a) Complaint Counsel's alleged post-fact discovery evidence related to Podster samples and in-depth investigations ("IDIs") that assisted Complaint Counsel's experts in forming the basis of their opinions in their direct written testimony submitted on April 28, 2023, and (b) testimony and documents related to the deficient warnings for the Podster.

(2) a *Daubert* motion to exclude Complaint Counsel's expert testimony on the grounds that: (a) each Complaint Counsel expert relies on the same post-fact discovery evidence (Podster samples and IDIs) discussed in the motion *in limine*, (b) the written testimony of Dr. Katwa and Ms. Kish related to the deficient warnings for the Podster is "unhelpful and irrelevant," (c) the written testimony of Dr. Mannen relies on the same IDIs that were alleged post-fact discovery evidence and her written testimony is "unreliable and irrelevant," (d) certain portions of Dr. Katwa's written testimony are allegedly outside of his proffered expertise, and (e) Dr. Katwa and Ms. Kish summarize the Podster IDIs (different and separate from the above IDIs) in their written testimony, which allegedly introduces fact testimony into their opinions.

Because of the overlap in issues addressed in each of Leachco's two motions, Complaint Counsel submits one opposition addressing both motions.

As further discussed below, Leachco's motion *in limine* is without merit because: (1) the prehearing schedule, equally applicable to the parties and agreed to by Leachco, permitted the disclosures in the time in which they were filed; (2) Leachco was not prejudiced by Complaint

Counsel's experts' use of Podster samples; and (3) the non-Podster IDIs that Leachco complains were either late-produced or not produced were used only for background purposes by Dr. Mannen and are otherwise irrelevant to this proceeding. Leachco's *Daubert* motion also fails because: (1) Complaint Counsel's expert testimony is reliable and relevant, and Leachco's generalized and unspecific claims must be raised on cross examination and not by excluding evidence; and (2) Complaint Counsel's expert testimony—based in part on other facts, data, and expert opinion—is wholly proper under this proceeding, the Federal Rules of Evidence, and caselaw.

Leachco misleadingly cites this Court's admonition—made in the context of Complaint Counsel's motion to compel Leachco to produce responsive electronic communications—that a sanction will be available if a party withheld materials from discovery that were then provided at hearing. *See* Feb. 24, 2023 Hearing Transcript, 33:14–34:5. However, and as detailed below, Complaint Counsel has not withheld such information and has complied with its discovery obligations and with any Court-ordered deadlines for providing information, including supplementing information when appropriate. As discussed below, each argument presented by Leachco is belied by the facts and procedural history of this case.

BACKGROUND

It is important to note the misstatements of the record and procedural history made by Leachco in its two motions and which form the basis for its arguments in such motions. After a discovery conference held on September 7, 2022, both parties submitted a "Joint Proposed Revised Prehearing Schedule" (Dkt. No. 33) for this Court's approval. This joint proposal was adopted by the Court in the September 16, 2022 Order on Prehearing Schedule (Dkt. No. 35). That Order, which was the same as agreed to by the parties, provided for a close of fact

discovery of March 20, 2023. However, the overall discovery deadline in the case was April 28, 2023, the same due date as the expert written direct testimony, as shown below:

Responses to Expert Interrogatories under 16 C.F.R. § 1025.31(c)(4)(i)(A) and Expert Witness Direct Testimony under 16 C.F.R. § 1025.44(b) and Discovery Deadline (pending motions to compel)	**April 28, 2023**

Conveniently, Leachco fails to mention this April 28 *overall* discovery deadline in both its motions. Further, as also agreed to by both parties, the expert discovery phase typical in federal district court litigation was condensed to just the filing of expert witness written direct testimony, with the opposing party having the opportunity to conduct cross-examination at the hearing in this matter. This is consistent with the Commission's Rules of Practice for Adjudicatory Proceedings which state that expert discovery should be limited in Commission adjudicatory proceedings:

> (4) *Hearing preparation: experts*. Discovery of facts known and opinions held by experts, otherwise discoverable under the provisions of paragraph (c)(1) of this section and acquired or developed in anticipation of litigation or for trial, may be obtained *only as follows*:
>
> (i) (A) A party may through interrogatories require any other party to identify each person whom the other party expects to call as an expert witness at trial, to state the subject matter on which the expert is expected to testify, to state the substance of the facts and opinions to which the expert is expected to testify, and to provide a summary of the grounds for each opinion.
>
> (B) Upon motion, the Presiding Officer may order further discovery by other means upon a showing of substantial cause and may exercise discretion to impose such conditions, if any, as are appropriate in the case.

16 C.F.R. § 1025.31(c)(4) (second emphasis added); *see also* § 1025.44(b)–(c) (directing the filing and exchange of expert written testimony no later than 10 days prior to the hearing and providing for the opportunity to conduct cross-examination); § 1025.1 ("A major concern of the Commission is that all matters in adjudication move forward in a timely manner.").

On April 28, 2023, pursuant to the Court's Order on Prehearing Schedule in this case, both parties filed and exchanged written testimony of their respective expert witnesses. To be clear, these were not expert reports, but instead written testimony that takes the place of the expert's direct testimony at the hearing. No expert reports were contemplated under the parties' Joint Proposed Revised Prehearing Schedule (Dkt. No. 33) or this Court's corresponding Order on Prehearing Schedule (Dkt. No. 35). Nor was any expert discovery agreed to by the parties outside of the exchange of expert written testimony and responses to expert interrogatories. On April 28, Complaint Counsel also responded to Leachco's expert interrogatories as directed by the Court's scheduling order.

The fact that Leachco now complains of prejudice at the eve of the hearing in this matter based on a prehearing schedule and procedural posture that Leachco agreed to months ago, proves the futility of its arguments in its two motions as discussed in greater detail below.

ARGUMENT

Pursuant to the Commission's Rules, "all relevant and reliable evidence is admissible" unless the Presiding Officer determines that "its probative value is substantially outweighed by unfair prejudice or confusion of the issues," or certain other factors apply. 16 C.F.R. § 1025.43(c). The Commission's Rules also note that "the Federal Rules of Evidence shall apply to all proceedings held pursuant to these Rules," but the Federal Rules of Evidence ("FRE") "may be relaxed by the Presiding Officer if the ends of justice will be better served by so doing." 16 C.F.R. § 1025.43(a).[1]

[1] *See also Conley v. N.L.R.B.*, 520 F.3d 629, 640 (6th Cir. 2008) ("[A]dministrative law judges are 'not obliged to strictly adhere to the Federal Rules of Evidence.'" (*citing 3750 Orange Place Ltd. P'ship v. N.L.R.B.*, 333 F.3d 646, 666 (6th Cir. 2003)); Wright & Miller, 32 Fed. Prac. & Proc. Judicial Review § 8237 (2d ed.) (May 2023 update) ("Generalizing, administrative tribunals take a much less strict approach to admissibility than federal trial courts. The obvious policy rationale for this relatively relaxed approach is that administrative tribunals need not, unlike federal courts, protect lay juries from evidence that they are purportedly likely to misunderstand.").

The Commission's Rules also define an expert witness:

> An expert witness is one who, by reason of education, training, experience, or profession, has peculiar knowledge concerning the subject matter to which his/her testimony relates and from which he/she may draw inferences based upon hypothetically stated facts or offer opinions from facts involving scientific or technical knowledge.

16 C.F.R. § 1025.44. This standard is consistent with FRE 702.

Expert testimony is admissible under FRE 702 if it concerns scientific, technical or other specialized knowledge that will aid the jury or other trier of fact to understand or resolve a fact in issue. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 592 (1993). In making this determination, the Court has the task of "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.* at 597.

In reviewing the admissibility of the testimony of potential experts, the Court has a "gatekeeper" role to exclude unreliable and irrelevant expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152–53 (1999); *but see Consolidation Coal Co. v. Dir., OWCP*, 294 F.3d 885, 893 (7th Cir. 2002) (noting that administrative litigations "are not bound by the specific evidentiary strictures of *Daubert*"); *Gibbs v. Gibbs,* 210 F.3d 491, 500 (5th Cir. 2000) ("Most of the safeguards provided for in *Daubert* are not as essential in a case such as this where a district judge sits as the trier of fact in place of a jury."); *Braggs v. Dunn*, No. 2:14cv601-MHT, 2017 WL 2984312, at *3 (M.D. Ala. July 13, 2017) ("[T]he *Daubert* barriers to admissibility are more relaxed in a bench trial, 'where the judge is serving as factfinder,' and the court need not be 'concerned about dumping a barrage of questionable scientific evidence on a jury.'") (citation omitted).

However, exclusion of expert testimony should never be the first step or preference for a court—instead, vigorous cross-examination of expert witnesses and presentation of contrary evidence should take the place of exclusion. *See Fish Farms P'ship v. Winston-Weaver Co.*, No.

2:09-CV-163, 2012 WL 12965440, at *1 (E.D. Tenn. Oct. 23, 2012), *aff'd*, 531 F. App'x 711 (6th Cir. 2013) ("As *Daubert* itself recognizes, vigorous cross examination is to be preferred to pretrial exclusion of expert testimony. . . . [I]f there is any serious doubt regarding the facts or data relied upon by an expert, then the resolution of that doubt should be left to the [trier of fact]."); *Hearts with Haiti, Inc. v. Kendrick*, No. 2:13-CV-00039-JAW, 2014 WL 4773479, at *5 n.5 (D. Me. Sep. 24, 2014) ("[T]he Supreme Court in *Daubert* preferred cross-examination, presentation of contrary evidence, and instructions on burden of proof over exclusion."); *see also Garcia v. Sec'y of Health & Hum. Servs.*, No. 05-0720V, 2010 WL 2507793, at *9 (Fed. Cl. May 19, 2010) ("Extremely rare will be the case where a party's expert witness is truly so patently unqualified to opine, or his opinion so unreliable in methodology, that exclusion from admission into evidence is warranted.")

I. Leachco Cannot Be Prejudiced By A Prehearing Schedule It Filed Jointly With Complaint Counsel

Most of Leachco's arguments in its two motions are based on either a misstatement or misunderstanding of the Court's Order on Prehearing Schedule (Dkt. No. 35) in this matter. Leachco, only a few weeks before the hearing in this matter, suddenly takes issue with the fact that there was a condensed expert discovery phase in this administrative litigation—a condensed phase expressly contemplated by this forum's rules. Leachco also omits from its motions the fact that the Court's prehearing schedule noted an overall discovery deadline of April 28, 2023.

As discussed above, this prehearing schedule was jointly proposed by the parties and entered as an Order by the Court over 10 months ago. Leachco cannot possibly claim any prejudice based on a schedule it jointly filed and proposed to the Court. Administrative proceedings under the Consumer Product Safety Act and its implementing regulations are designed to streamline and expedite prehearing discovery due to the potential harm to consumers

if a consumer product is found to be a substantial product hazard. As such, Commission regulations do not provide for an expert discovery phase as is typical in federal district court litigation.[2] Pursuant to the Court's Order and the rules that govern this proceeding, no expert reports were filed and no expert depositions were taken. This cannot possibly prejudice Leachco because the same rules applied to Complaint Counsel: Complaint Counsel did not have the benefit of reviewing expert reports produced by Leachco or deposing Leachco's expert prior to submitting its written expert direct testimony.

The Commission's Rules specifically limit expert discovery to interrogatories that "identify each person whom the other party expects to call as an expert witness at trial, to state the subject matter on which the expert is expected to testify, to state the substance of the facts and opinions to which the expert is expected to testify, and to provide a summary of the grounds for each opinion." *See* 16 C.F.R. § 1025.31(c)(4)(i)(A). Any further expert discovery is only available upon motion to the Presiding Officer and requires a showing of "substantial cause." *Id.* § 1025.31(c)(4)(i)(B). Leachco did not file any motion with the Court seeking an expansion of expert discovery in this case, much less shown the higher bar of substantial cause. And Complaint Counsel complied with the requirements of § 1025.31(c)(4)(i)(A) by supplementing its responses to Leachco's expert interrogatories on April 28, 2023. Therefore, Leachco cannot possibly claim any prejudice.

Further, Leachco conveniently omits from its motions a key detail in the prehearing schedule: while fact discovery closed on March 20, April 28 was the overall discovery deadline

[2] Thus, most of the federal district court case law cited and relied on by Leachco in its two motions is inapplicable here. As discussed above, there were no expert reports filed in this matter because the parties agreed to an expedited expert discovery phase as contemplated by the Commission's Rules. Thus, all case law that Leachco cites interpreting the Federal Rules of Civil Procedure as they relate to expert discovery and expert reports is not applicable to this proceeding.

in this case. *See* Dkt. No. 35, at 1. Thus, Complaint Counsel's production of written testimony, supplementation of its responses and objections to Leachco's expert interrogatories, and additional documents produced after the March 20 date still were timely under the agreed-upon discovery deadline of April 28.

II. Complaint Counsel's Expert Analysis Of Podster Samples, Which Leachco Chose Not To Inspect, Resulted In No Prejudice to Leachco

Leachco, the *manufacturer* of the Podster, somehow argues that it is severely prejudiced because it does not have access to Podsters. It makes two separate but similar arguments for exclusion of evidence and testimony based on Podster samples that were reviewed by Complaint Counsel's experts as part of their analysis of the Podster and allegedly not provided to Leachco for inspection: (1) that the Court should exclude all Podster samples relied on by Complaint Counsel's experts (Leachco MiL, at 10–11), and (2) that the written testimony of Dr. Mannen, Dr. Katwa, and Ms. Kish should be excluded because each expert relied on these Podster samples in forming their opinions (Leachco Daubert Motion, at 6–9). Each argument fails.

The issue in this case is whether the general design of the Podster presents a substantial product hazard. This case is not about any manufacturing defect or post-purchase modification by consumers of the Podster that could have created a hazard with specific incident samples.

[redacted][3] Thus, there is no reason why Leachco would need to inspect the *identical* Podster samples that Complaint Counsel's experts inspected in forming their expert opinions. Leachco has unfettered access to Podster samples as the manufacturer of the product. It could have easily

[3] [redacted]

allowed its own expert witnesses to inspect any number of Podster samples in its possession. Thus, even if Leachco is correct that it somehow had the right to inspect the *identical* Podster samples that Complaint Counsel's experts reviewed, it could not have suffered "severe prejudice," Leachco MiL, at 10, by this omission because the Podsters that Complaint Counsel's experts examined were identical to any Podster that Leachco could have shown its expert witness.

Further, Leachco's argument is belied by a quick review of Dr. Mannen's expert written testimony. Nowhere in Dr. Mannen's testimony does she state that her opinions are limited only to the Podsters that she inspected—to the contrary, she notes that all Podster models she reviewed were "substantially similar"[4] and does not mention anything particular about the samples she analyzed that would differ from any other Podster product.

Despite the above, Complaint Counsel still told Leachco it could inspect certain Podsters it had purchased and analyzed as part of its pre-suit investigation.[5] ***But Leachco never scheduled an inspection***. In response to Leachco's Request for Production No. 50, Complaint Counsel responded (on May 13, 2022, 10 months prior to the close of fact discovery): [redacted][6]

Further, in response to Leachco's Interrogatory No. 36, also served on Leachco on May 13, 2022, Complaint Counsel told Leachco exactly where they acquired these Podster samples:

[4] *See* Expert Testimony of Erin Mannen, Ph.D. (Apr. 28, 2023), CCX-1, at 13 n.5.
[5] As discussed in detail below, Podsters purchased for Dr. Mannen's testimony would not be discoverable under the Commission's rules as they were tested and analyzed in anticipation of litigation. *See* 16 C.F.R. § 1025.31(c)(4).
[6] *See* Complaint Counsel's Objections and Responses to Respondent's First Set of Requests for Production of Documents and Things to Consumer Product Safety Commission, at 49 (May 13, 2022) (Exhibit 1).

[redacted][7]

It is inconceivable that Leachco now claims "severe prejudice," Leachco MiL, at 10, regarding an inspection of Podster samples that they never reached out to Complaint Counsel to schedule. Any prejudice allegedly suffered by Leachco is due to its own inaction. *See Fairlane Car Wash, Inc. v. Knight Enterprises, Inc.*, No. 07-CV-10165, 2008 WL 1882659, at *1 (E.D. Mich. Apr. 24, 2008) (denying in part motion *in limine* to exclude documentation of alleged damages where "any prejudice is a consequence of Defendant's failure to inspect the supporting documentation, not Plaintiff's failure to disclose it or otherwise make it available"); *Fick v. Exxon Mobil Corp*., No. CV 13-6608, 2017 WL 73126, at *1 (E.D. La. Jan. 5, 2017) (denying defendant's motion to exclude a photograph when "[Defendant] could have inspected the photograph . . . earlier, and any failure is due to its own decisions, rather than any unfair prejudice").

Finally, the additional 10 Podster samples that Leachco complains about not having access to, Leachco Daubert Motion, at 5, were requested by Dr. Mannen and purchased for her by CPSC staff after the filing of the complaint, and thus, would not be discoverable by Leachco. These Podster exemplar samples were purchased online by CPSC internet investigative staff in May 2022 through Bed Bath & Beyond and Buy Buy Baby. As noted above, in this proceeding, "[d]iscovery of facts known and opinions held by experts, otherwise discoverable under the provisions of paragraph (c)(1) of this section and acquired or developed in anticipation of

[7] See Complaint Counsel's Objections and Responses to Respondent's First Set of Interrogatories to Consumer Product Safety Commission, at 45–46 (May 13, 2022) (Exhibit 2).

litigation or for trial, may be obtained only" through limited interrogatories or through a showing of substantial cause. 16 C.F.R. § 1025.31(c)(4). Thus, information about the 10 Podsters Dr. Mannen evaluated in her report—which were uncontestably purchased and analyzed in anticipation of and for the purpose of this litigation—was properly disclosed by Complaint Counsel when it served Dr. Mannen's expert testimony on April 28, 2023.

III. The 136 Non-Podster IDIs Referenced By Dr. Mannen In Her Written Testimony Are Not Part Of Complaint Counsel's Exhibit List Or Affirmative Case

Additionally, Leachco claims prejudice based on 136 IDIs that were either allegedly late-produced or never produced to them by Complaint Counsel. This is again an exaggeration of the facts involved—the truth is, as Leachco surely is aware, these 136 IDIs were background, supplemental information that Dr. Mannen reviewed when performing her prior Commission research. Notably, all of these IDIs at issue "relate to other infant products," not the Podster specifically, as admitted by Leachco. *See* Leachco MiL, at 6. The three Podster-specific IDIs are separate and distinct from these other 136 IDIs.

Leachco specifically requests that: (1) the Court should exclude all 136 IDIs relied on by Dr. Mannen (Leachco MiL, at 10–11), and (2) the written testimony of Dr. Mannen should be excluded because she relied on these 136 IDIs in forming her opinions (Leachco Daubert Motion, at 6–9, 12–14). Each of these arguments by Leachco fail for the following reasons.

First, Complaint Counsel does not intend to use any of these 136 IDIs in its affirmative case. None of these 136 IDIs were listed in Complaint Counsel's Exhibit List filed on July 14 and Complaint Counsel has been consistent throughout this proceeding that these 136 IDIs concerning other infant lounger and sleep products are not relevant to this proceeding concerning the Leachco Podster specifically. For her research on inclined sleep products, Dr. Mannen reviewed 191 IDIs to "qualitatively assess trends, similarities, or differences" among infant

injuries and deaths that occurred in the products.[8] The IDIs were categorized with reference to the position of the infant and relevant factors such as age, use of the product's restraint, health, and prematurity.[9] Similarly, for the 2022 infant pillow study, Dr. Mannen sorted the IDIs into categories based on incident type and other relevant factors.[10] Neither of Dr. Mannen's prior reports refers to any individual IDI, nor do they rely on the IDIs for any purpose other than to establish potential injury patterns.

Second, Dr. Mannen's opinions and testing in her written testimony do not rely on these IDIs—they were merely supplemental information that she reviewed as a basis for setting up her experiments for testing the Podster's design attributes. Dr. Mannen stated as much, noting that the prior studies "serve as a backdrop to my expert analysis of the Podster."[11] She then described in detail how she tested and evaluated the Podster's characteristics *specifically*, not simply relying on prior work to make conclusions about the Podster.[12] However, in the spirit of transparency, Complaint Counsel produced to Leachco a subset of these non-Podster IDIs—by the April 28 discovery deadline—which were related to Dr. Mannen's 2022 Pillows Product Characterization and Testing report as a courtesy when CPSC submitted her expert testimony.

Third, case law is clear that experts may rely on evidence not in the record to form their opinions. *See, e.g.*, *Werth v. Makita Elec. Works, Ltd.*, 950 F.2d 643, 648 (10th Cir. 1991) ("[T]he expert may rely on facts outside the record and not personally observed, but of the kind that experts in his or her field reasonably rely on in forming opinions.") (citations omitted); *Mattingly v. Home Depot U.S.A., Inc.*, No. 1:08–CV–341, 2009 WL 10676568, at *6 (E.D. Tex.

[8] Expert Testimony of Erin Mannen, Ph.D. (Apr. 28, 2023), CCX-1, at 102–05.
[9] *Id.* at 170–73.
[10] *Id.* at 189–95.
[11] *Id.* at 11.
[12] *See id.* at 11–31.

Oct. 20, 2009) ("[I]f the facts and data upon which an expert relies in forming an opinion are of a type reasonably relied upon by other experts in the particular field, the facts and data themselves need not be admissible in order for the opinion to be admitted.") (citations omitted). Specific incident information is the type of information that expert witnesses typically reference in forming their opinions about safety hazards. Thus, there is nothing wrong with Dr. Mannen using IDIs not of record here that are otherwise irrelevant to these proceedings in helping set up the test parameters for her Podster experiments.

Leachco cannot suffer any prejudice from the non-disclosure or alleged late disclosure of these non-Podster IDIs which will not be relied upon by Complaint Counsel in its affirmative case and which Complaint Counsel agrees are irrelevant to this specific proceeding regarding the Podster.

IV. Testimony Related To The Podster's Deficient Warnings/Instructions And Overall Deficient Warning System Assist In Proving Reasonably Foreseeable Use Of The Podster

As was discussed in detail in Complaint Counsel's Prehearing Brief (Dkt. No. 101), the relevant inquiry in this proceeding is whether Leachco's Podsters present a substantial product hazard because they have "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2). The Commission's regulation defining a defect is applicable in this proceeding. *See* 16 C.F.R. § 1115.4; *see also* Order Denying Complaint Counsel's Motion for Partial Summary Decision Order Denying Respondent's Motion for Summary Decision (Jul. 6, 2023), Dkt. No. 99, at 6 n.7.

The Commission's regulation is instructive in broadly providing guidance regarding product defects under the CPSA. The regulation notes that a defect "may be the result of a manufacturing or production error," or that a defect "can also occur in a product's contents,

construction, finish, packaging, warnings, and/or instructions." 16 C.F.R. § 1115.4. The regulation also provides guidance on design defects, noting that a design defect may be present "even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public." *Id.* Further, a design defect may also be present "if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended," and a "risk of injury" includes "a risk of death, personal injury, or serious or frequent illness." *Id.*; CPSA § 3(a)(14), 15 U.S.C. § 2052(a)(14). In determining whether a risk of injury renders a product defective, the Commission considers the following factors, as appropriate:

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

16 C.F.R. § 1115.4 (emphasis added).

As Leachco notes, Complaint Counsel is alleging that the Podster contains design defects which create a substantial risk of injury to the public. However, that does not mean that Complaint Counsel cannot provide expert testimony showing that the Podster's instructions and warnings do not adequately prevent misuse or mitigate against the dangers of misuse; in fact, and as noted above, that is a factor to be considered in proving whether the risk of injury associated with a product renders such product defective. Further, Complaint Counsel has alleged, and provided detailed expert testimony, that "it is foreseeable that consumers will use the Podster for infant sleep, for co-sleeping in an adult bed, on elevated surfaces, and in other infant products, such as cribs" despite Leachco's instructions and warnings, that "consumers will not constantly

supervise infants while they are in the Podster" despite Leachco's instructions and warnings, and that "the Podster's marketing, instructions, warnings and packaging do not mitigate the risk of suffocation and death for infants."[13] Although Leachco misses the point, an evaluation of whether it is *reasonably* foreseeable that consumers will use the Podster for sleep or without constant supervision because of the lack of adequate warnings and instructions—and whether such warnings can even mitigate against the hazard—involves an inquiry into such warnings and instructions, and is part of the overall analysis as to whether the Podster poses a substantial product hazard.

This legal framework for Complaint Counsel's allegations that the warnings and instructions would not mitigate the hazard and that consumers (reasonably) would use the Podster for sleep and without supervision was specifically detailed in the Complaint. Paragraphs 14–19 of the Complaint identify the various warnings and instructions that accompany the Podster; however, paragraph 20 notes that "*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." Compl. ¶¶ 14–20 (emphasis added). Paragraph 20.a. goes one step further, noting that "it is *foreseeable* that some caregivers may *disregard or not fully read the Podsters' warnings*." Compl. ¶¶ 20.a. (emphasis added). This is echoed by paragraph 38, which notes, again, that "[i]t is *foreseeable* that caregivers will use the Podster for infant sleep, *despite the instructions and warnings*. It is also *foreseeable* that caregivers will use the Podster without supervision." Compl. ¶¶ 38 (emphasis added). Indeed, Leachco admits that "the Commission's key allegation is that 'it is foreseeable' that the Podster will be misused." *See* Leachco Daubert Motion, at 1. Thus, it was evident from the Complaint—and Leachco had

[13] Expert Testimony of Celestine T. Kish, M.A. (May 2, 2023), CCX-2, at 1–2.

plenty of notice—that although Complaint Counsel was not alleging an instructions or warnings defect, the efficacy of such instructions and warnings as it pertains to consumer use and risks to infants is a factual issue in dispute in this proceeding.

While Leachco may claim that it misunderstood this legal theory, its claim of surprise and that it "did not focus on the warnings, instructions, and marketing during discovery," *see* Leachco MiL, at 14, is a complete misrepresentation. Aside from being aware of the allegations in the Complaint, one of the first documents Complaint Counsel produced to Leachco in this matter was Product Safety Assessment ("PSA") 0598.21, which provides a detailed evaluation of the instructions and warnings associated with the Podster.[14] This PSA, which was one of the evidentiary bases for requesting authorization of the Complaint, discusses how some "caregivers may not fully read and understand the warning information," or that caregivers who may be aware of safety messages may use such product "even if it contradicts safety messaging or safe sleep practices." *Id.* at 16–17. Additionally, the PSA notes that CPSC technical staff did not believe that changes to the product packaging or warnings "will have a significant effect on consumer behavior." *Id.* at 15.

Further, Leachco was able to test these conclusions during the deposition it noticed of Zachary Foster, the CPSC technical officer that drafted PSA 0598.21. Leachco conducted a lengthy examination regarding the PSA and the warnings and instructions.[15] [redacted]

[14] *See generally* JX-34 (produced to Leachco on April 8, 2022).
[15] *See* Deposition of Zachary Foster, at 26:1–187:5 (Mar. 8, 2023) (Exhibit 3).

[redacted][16]

Federal courts have previously rejected arguments of unfair surprise where, as here, parties were on notice of relevant facts that were discussed during a deposition. *See Ramirez v. OMBS Security System LLC*, No. 19-20216, 2021 WL 4992569, at *2 (S.D. Fl. Aug. 20, 2021) (denying motion to exclude evidence pertaining to legal issue not raised in the complaint: "because the issue was raised during Plaintiff's deposition and the deposition of [non-party] Ana Nadal, Defendants cannot claim unfair surprise") (*citing Connelly v. Gen. Med. Corp.*, 880 F. Supp. 1100, 1110 (E.D. Va. 1995) ("Because these facts came to light during the depositions of probable defense witnesses, the defendants cannot claim to be unfairly surprised.")).

Thus, Leachco's vague statement that it was unable to "focus" on the warnings and instructions in discovery, is simply false—it was provided information by Complaint Counsel and even deposed CPSC's technical staff regarding its evaluation of the instructions and warnings. This suspect claim, however, is belied further by Leachco's own expert testimony filed on April 28, 2023. [redacted][17] [redacted][18]

[16] Exhibit 3, at 75:7–76:6.
[17] Expert Testimony of Peggy Shibata (Apr. 28, 2023), RX 1, at 3.
[18] RX 1, at 8–9.

[redacted][19] There is simply no basis for Leachco to claim that it was unaware or unable to "focus" on the warnings and instructions in discovery. *See Martin v. J.A.M. Distributing Co.*, No. 1:08-CV-298, 2009 WL 10677609, at *2 (E.D. Tex. Apr. 9. 2009) (denying motion to strike a late-identified expert on attorneys' fees, reasoning, "[Defendant] has no viable argument of unfair surprise or prejudice because it has already designated its own expert on the issue of attorneys' fees"); *Citizens Federal Bank, FSB v. United States*, 59 Fed. Cl. 507, 513 (Fed. Cl. 2004) (rejecting an argument that plaintiff's damages theory was untimely where the defendant's "own expert raised the issue," undermining the claim of unfair surprise).

In its two motions, Leachco cites various statements in Complaint Counsel's Interrogatories regarding the warnings and instructions; however, none are inconsistent with the above-referenced approach. Again, the efficacy of the instructions and warnings is directly related to the evidence that the Podster poses a substantial product hazard; not only was Leachco provided plenty of notice about these issues, it took actions to respond to these issues affirmatively.[20]

In any event, and as shown above, Leachco's claim of surprise is meritless. Leachco's misplaced arguments primarily rely on irrelevant precedent concerning failure to comply with certain express Required Disclosure requirements of Fed. R. Civ. P. 26, which does not apply to this proceeding and has no analog under the Commission's Rules. *See MLC Intell. Prop., LLC v.*

[19] RX 1, at 12–14.
[20] It is the position of Complaint Counsel, as noted throughout the various filings in this matter, that no warning could mitigate against the defects posed by the Podster's design. Thus, Complaint Counsel chose not to pursue a defective instructions and warnings count because no remedy exists to cure such defective instructions and warnings.

Micron Tech., Inc., 10 F.4th 1358, 1370 (Fed. Cir. 2021) (concerning failure to timely disclose "a computation of each category of damages claimed," as expressly required under Rule 26(a)(1)(A)(iii)); *Aetna Inc. v. Mednax, Inc.*, No. 18-2217, 2021 WL 949454, at *6 (E.D. Penn. Mar. 12, 2021) (same); *Igenco Holdings, LLC v. Ace Am. Ins. Co.*, 921 F.3d 803 821–22 (9th Cir. 2019) (same); *see also Masimo Corp v. Apple, Inc.*, No. SA CV 20-00048 JVS, 2022 WL 18285029, at *7 (C.D. Cal. Nov. 22, 2022) (concerning failure to provide written reports of retained expert witnesses as required under Rule 26(a)(2)(B)).

Here, Leachco was well aware of Complaint Counsel's allegations that consumers would (foreseeably) use the Podster for sleep and for unsupervised use. Leachco was also aware that Complaint Counsel was alleging that no warning or instruction could mitigate against the hazard. Further, Leachco took affirmative steps to respond to these allegations, by eliciting deposition testimony of CPSC staff and through discussion in Ms. Shibata's expert testimony. There is thus no basis to exclude Complaint Counsel's expert testimony on warnings and instructions.

V. Dr. Mannen's Written Testimony Is Both Reliable And Relevant

Leachco additionally argues that the mere citation to Commission IDIs[21] in Dr. Mannen's written testimony renders her entire testimony "unreliable and irrelevant" because these documents only provide anecdotal information and not reliable scientific evidence. Leachco Daubert Motion, at 14. This argument is flawed for several reasons.

First, it is Leachco's burden to raise specific challenges to the expert testimony it seeks to exclude. Leachco cannot merely cite vague, generalized challenges to the reliability of Complaint Counsel's expert witnesses and rely on this Court (or Complaint Counsel) to try and figure out what exactly it is attempting to exclude. *See DAC Surgical Partners, P.A. v. United*

[21] It is unclear which Commission IDIs Leachco is referring to here, the 136 non-Podster IDIs or the three Podster-specific IDIs, or both.

Healthcare Servs., Inc., No. 11-CV-01355, 2014 WL 4684834, at *3 (S.D. Tex. Jul. 31, 2014) (denying a motion to exclude defendants' expert report as unreliable where plaintiffs "do not point to any particular opinions contained in the Mayo Report, but instead argue only generally that all the opinions should be excluded on reliability grounds. [Plaintiffs'] vague and generalized reliability arguments do not, and cannot support the wholesale exclusion of Mayo and his opinions"); *Goldberg v. 401 N. Wabash Venture LLC*, No. 09 C 6455, 2013 WL 212912, at *2 n.1 (N.D. Ill. Jan. 18, 2013) (explaining that the party seeking exclusion "bear[s] the burden of bringing to the Court's attention any specific opinions with deficiencies. It is not the responsibility of the Court to review [a] seventy-two page report and *sua sponte* determine which statements meet the mandates of *Daubert*").

Here, Leachco cites vaguely to "Commission IDIs" that allegedly form the basis of excluding Dr. Mannen's written expert testimony as "unreliable and irrelevant" without providing any explanation of what specific IDIs it is referring to, or what portions of Dr. Mannen's testimony should be excluded on that basis. As such, Leachco has not met its burden and the Court should deny this argument outright.

Second, if Leachco takes issue with the three Podster IDIs, Complaint Counsel explained in its July 14 motion *in limine* that Commission IDIs are official, legally-authorized public records of CPSC Field staff investigations of specific incidents related to consumer products, and include factual findings based on interviews of eyewitnesses, official police/fire/medical reports, and, when applicable, investigation of the consumer product and scene of the incident. The mere citation to any Commission IDI does not render an expert's opinion unreliable.

Third, Dr. Mannen did not actually rely on any "Commission IDI" as a basis for her written testimony. As part of her prior work with the Commission and during her analysis of the

Podster for this proceeding, Dr. Mannen reviewed various Commission IDIs concerning other infant sleep and infant lounger products manufactured by other companies. Dr. Mannen also reviewed the three IDIs related to Podster-specific fatal incidents. However, in forming her expert opinions in this case, Dr. Mannen performed reliable, scientifically-based experiments on actual Podster samples. She did not merely review incidents concerning the Podster and other infant sleep/lounger products and base her opinions only on those incidents. These Commission IDIs informed how she set up and performed her testing of the Podster, by providing real-world data for how infants can suffocate in infant sleep and lounger products. This testing is the basis for her opinions that the Podster design is defective, not any "Commission IDI."

For example, Dr. Mannen specifically mentions in her written testimony how she used these "Commission IDIs":

> In 2022, our multidisciplinary team of engineers, clinicians, and researchers conducted research to analyze the death or injury risk to infants associated with the use of infant pillows, including nursing pillows and other types of pillows that are marketed as aiding or supporting infants, in various ways, such as in the context of feeding, nursing, sleeping, propping, and lounging (hereafter referred to as "pillows"). This work resulted in a study titled "Pillows Product Characterization and Testing."
>
> In connection with that study, we reviewed 50 in-depth investigation (IDI) documents provided to us by the CPSC. Our review of the IDIs elucidated that suffocation-related hazards occur in infant pillow products in two main ways: (1) occlusion or rebreathing, meaning the nose or mouth is occluded by contact with the product or the infant's face is in contact or near contact with a product that promotes CO2 rebreathing; and (2) positional asphyxia, meaning that the infant's body position (trunk flexion, chin-to-chest position, and/or neck hyperextension) inhibits normal breathing. In our study, we explored both suffocation hazard types by designing and conducting tests to measure product characteristics that would be dangerous for both suffocation scenarios: occlusion and positional asphyxia. [22]

As can be seen from this passage, Dr. Mannen studied the incident reports in these IDIs to understand how infants were suffocating in these infant loungers: either by occlusion/rebreathing

[22] Expert Testimony of Erin Mannen, Ph.D. (Apr. 28, 2023), CCX-1, at 10.

or by positional asphyxia. This background information helped set up her test parameters for infant loungers in her 2022 study. Those same test parameters were used to further test the suffocation risk presented by the Podster through her work as an expert in this matter.

There should be no dispute concerning the scientific methodology employed by Dr. Mannen in her written testimony. She uses "commonly known testing techniques . . . that have been used in peer-reviewed research on infants since the 1980s" and are "accepted within the biomechanical community as the most reliable and recognized methods of biomechanical data collection."[23] Instead of trying to exclude this reliable scientific evidence (which Leachco cannot do), Leachco instead conjures up a fictitious explanation of Dr. Mannen's testimony that relies on "Commission IDIs" and no scientific evidence in the hopes that it might fool this Court into excluding her written testimony. The Court should not fall for this ruse. It is clear from a quick review of Dr. Mannen's written expert testimony that her testimony is based on well-known scientific principles and is thus both reliable and relevant to this proceeding.

VI. Dr. Katwa's Written Testimony Is Wholly Within His Proffered Expertise

Leachco cites several portions of Dr. Katwa's testimony as evidence that Dr. Katwa is offering "opinions" on the topics of "product design, biomechanical engineering, marketing, and consumer behavior," but Dr. Katwa has not offered opinions outside of his areas of expertise. Dr. Katwa is a medical doctor, board-certified pediatric pulmonologist, and sleep specialist who is the medical director of a renowned sleep center at Boston Children's Hospital that treats thousands of patients a year, and his testimony explains the risk of injury created by the Podster's design as well as certain areas of consumer behavior and infant movement as to which he has gained insight through his clinical work that would be helpful to the trier of fact in this

[23] *See id.* at 10–11.

matter.[24] According to Dr. Katwa's testimony, the neck flexion or trunk flexion created by the Podster can lead to positional asphyxia, and infants who roll or move into a position in which the Podster's soft surface obstructs their nose and mouth may suffer "prolonged hypoxemia and elevated CO_2 due to reduced airflow and rebreathing of expired air," which "can result in brain hypoxia, low heart rate, reduced blood flow to the body particularly the brain, loss of consciousness, cardiorespiratory arrest and eventually death."[25] His opinion necessarily considers the manner in which caregivers will foreseeably use the Podster, the positioning of an infant's body within the Podster, an infant's ability to slide down in the product, and the Podster's design characteristics. Because he is not an expert in biomechanical engineering or human factors, he generally relies on the opinions of Dr. Mannen and Ms. Kish as a foundation for his own opinions but also draws from the expertise he has gained from treating thousands of patients.[26]

The first statement of Dr. Katwa's cited by Leachco is that "'in effect,' the Podster 'acts like' an inclined sleeper." Leachco Daubert Motion, at 16. This appears in Dr. Katwa's testimony under the heading "Overview of the Design of the Podster."[27] Dr. Katwa refers to the American Academy of Pediatrics' 2022 policy statement on safe sleep, which recommends a firm, flat sleep surface.[28] Dr. Katwa observes that the Podster does not constitute a firm sleeping surface, and states that "the Podster acts like an inclined sleep product"—in other words, the Podster is also not a *flat* sleeping surface.[29] Contrary to Leachco's argument, this factual observation

[24] *See* Expert Testimony of Umakanth Katwa, M.B.B.S., M.D. (Apr. 28, 2023), CCX-3, at 38.
[25] *Id.* at 30.
[26] *See id.* at 5 (noting that to conduct his analysis of the Podster, Dr. Katwa "reviewed the data Dr. Erin Mannen collected from her biomechanical testing of the Leachco Podster product" and "reviewed Celestine Kish's expert testimony in this matter").
[27] *Id.* at 17.
[28] *Id.*, Reference 1.
[29] *Id.*; *see also id.* at 25 (referring to Dr. Mannen's testing showing that the Podster's incline exceeds 10 degrees).

regarding the Podster's design is not opinion testimony on "product design." No special expertise is required to observe that the Podster maintains infants in an inclined and non-flat position—indeed, Leachco's own marketing, which Dr. Katwa included as an exhibit to his testimony, states that the product is marketed to "provide[] upper body elevation."[30] It follows, as noted by Dr. Mannen, that if an infant were to sleep in the Podster, the Podster would create incline angles similar to an inclined sleep product.[31]

In the same "Overview" section, Dr. Katwa further describes the position in which the Podster maintains an infant and the potential that infants can move into other positions due to the Podster's design. Even without citations, Leachco recognized the assertions in this section as the findings and opinions of Dr. Mannen, not Dr. Katwa, but still argues that they should be excluded on the basis that Dr. Katwa does not have expertise in biomechanical engineering. *See* Leachco Daubert Motion, at 17. Leachco also disregards the fact that Dr. Katwa has observed and discussed with thousands of patients using infant products and so he does have unique and helpful insight into infant movement in consumer products. Leachco seems to believe that one must be both an expert in biomechanical engineering and a medical doctor to be allowed to testify as to the medical consequences of using the Podster for sleep, [redacted].[32]

Nothing prevents an expert witness from relying on the opinions of experts in areas outside the testifying expert's own field of expertise. In fact, the case cited by Leachco supports this proposition. In *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, the Seventh Circuit discussed whether an expert was qualified to testify when the affidavits of other (non-testifying)

[30] *Id.*, Ex. B.
[31] *See* Expert Testimony of Erin Mannen, Ph.D. (Apr. 28, 2023), CCX-1, at 13–15.
[32] *See* Expert Testimony of Peggy Shibata (Apr. 28, 2023), RX-1, at App'x A.

experts on which his opinion relied had been stricken due to late disclosure. 285 F.3d 609 (7th Cir. 2002). The court considered the nature of the work they performed, which involved considerable technical expertise beyond mere data collection. *Id.* at 614–15. The full paragraph in which the portion quoted by Leachco (in italics below) appears reads:

> The *Daubert* test must be applied with due regard for the specialization of modern science. *A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty.* That would not be responsible science. A theoretical economist, however able, would not be allowed to testify to the findings of an econometric study conducted by another economist if he lacked expertise in econometrics and the study raised questions only an econometrician could answer. If it were apparent that the study was not cut and dried, the author would have to testify; he could not hide behind the theoretician.

Id. at 614.

The issue raised by Leachco would only arise if Dr. Mannen and Ms. Kish were not testifying. In *Dura Automotive Systems*, the trial court found the expert to be unqualified to testify because the affiants who performed the analysis underlying his opinion were *not* permitted to testify, and their testimony would have been required because their work constituted "expert opinions, not recitations of cut-and-dried procedures." *Id.* at 615–16. Since all three experts here have submitted written testimony and will appear at the hearing in this matter, there is no problem: Dr. Mannen and Ms. Kish are not "hiding behind" Dr. Katwa, and Dr. Katwa is not acting as the "mouthpiece" of the other two experts.

Leachco also argues that Dr. Katwa should not be allowed to opine on the unsupported health claims found in Leachco's marketing because he is not an expert in "marketing or in the effect of marketing on consumer behavior." Leachco Daubert Motion, at 17. Dr. Katwa is not offering an opinion on marketing or the effect of marketing on consumer behavior; he is specifically responding to Leachco's claim that the Podster "provides upper body elevation which can help aid in digestion and breathing." Dr. Katwa's opinion that Leachco's claim is

misleading and harmful is well within his expertise as a medical doctor, and the basis for this opinion is thoroughly explained in his written testimony.[33] The sole reference to consumer behavior in this section is that "Leachco's marketing can cause caregivers to forego seeking the advice of … medical professionals, and, instead, buy these products to help with baby breathing or reflux symptoms." *Id.* This is hardly a controversial statement; no specialized training or knowledge is required to understand that Leachco's misleading health claims may lead caregivers to believe that an infant's reflux or breathing difficulties can be remedied by using the Podster to prop up the infant. Dr. Katwa's testimony explains how infants can be harmed by the Podster if caregivers use the product to treat these medical issues on their own.

Leachco also quotes, without context, *Ralston v. Smith & Nephew Richards, Inc.*, another case that is inapplicable to its argument here. *See* Leachco Daubert Motion, at 17. In *Ralston*, a plaintiff suing a medical device manufacturer on failure to warn grounds presented the testimony of an orthopedic surgeon who had no expertise in the type of device at issue, and, according to the expert's own deposition testimony, she had not even been asked to testify on the adequacy of the warnings. 275 F.3d 965, 967–69 (10th Cir. 2001). The Tenth Circuit held it was not an abuse of discretion to exclude the expert's testimony based on her lack of qualifications in the subject area. *Id.* at 970. Here, as discussed above, Dr. Katwa is not offering opinions outside of his area of expertise, and any such opinions that appear within his testimony are those of other testifying experts.

Thus, Leachco has provided no basis to exclude the testimony of Dr. Katwa. Dr. Katwa's testimony is based on his proffered expertise and, where applicable, references the testimony of Complaint Counsel's other testifying expert witnesses to fill in certain gaps. This is permissible

[33] Expert Testimony of Umakanth Katwa, M.B.B.S., M.D. (Apr. 28, 2023), CCX-3, at 29.

where a party requires the use of multiple expert witnesses and is not a basis for exclusion of an expert's testimony. *See* Fed. R. Evid. 703; *see also Dura Automotive Systems*, *supra*, at 612–13 ("Now it is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert.").

VII. It Is Proper For Complaint Counsel's Expert Witnesses To Summarize The Podster IDIs

It is completely appropriate for an expert witness to summarize government-authorized investigations of incidents. *See, e.g.*, *United States v. DeSimone*, 488 F.3d 561, 576–77 (1st Cir. 2007). Leachco has pointed to no reason why this is not permissible; in fact, [redacted][34] Indeed, it is difficult to respond to Leachco's argument because its *Daubert* motion provides no valid factual or legal argument supporting exclusion of the testimony. Leachco cites no example where any of Complaint Counsel's experts "offer fact testimony as if they had been percipient witnesses." *See* Leachco Daubert Motion, at 18. Nor does Leachco allege that any summary of IDIs by Complaint Counsel's experts is inaccurate; it simply makes unsupported allegations that Dr. Katwa "speculated" regarding the Texas incident and "attempts to resolve disputes" regarding the Alabama incident.[35] Dr. Katwa was not making up facts, as Leachco seems to suggest. He was reviewing these official reports and other documents and applying his expertise as a doctor to confirm and explain the circumstances surrounding the incident.[36]

[34] *See* Expert Testimony of Peggy Shibata (Apr. 28, 2023), RX 1, at 4–5.

[35] To the contrary, the IDIs demonstrate that the experts' summaries are accurate. [redacted]

[36] *See, e.g.*, Expert Testimony of Umakanth Katwa, M.B.B.S., M.D. (Apr. 28, 2023), CCX-3, at 27 ([redacted]

The case cited by Leachco in support of excluding this portion of the experts' testimony, *Stephens v. Union Pacific R.R. Co.*, 935 F.3d 852 (9th Cir. 2019), is completely inapposite here. In *Stephens*, the plaintiff relied on experts to provide evidence of his asbestos exposure when his own testimony "was, at best, barely sufficient to show any exposure at all." *Id.* at 856–57. The Ninth Circuit held that it was appropriate for the District Court to grant summary judgment in favor of Union Pacific, because Plaintiff needed evidence of "exactly what happened," and this was "not a subject on which Stephens's experts have any expertise—or any other basis for knowledge—so their testimony cannot fill in the evidentiary gap." *Id.* at 857.

There is no such "evidentiary gap" here: the IDIs contain official reports and witness statements that provide evidence regarding the incidents. Nor does the fact that the experts did not witness the incidents justify striking their testimony. Under FRE 703, experts need not be percipient witnesses: "An expert may base an opinion on facts or data in the case that the expert *has been made aware of* or personally observed." Fed. R. Evid. 703 (emphasis added). Leachco has not disputed the reliability of the IDIs themselves and its own expert has relied on them in her testimony. Additionally, as was explained in Complaint Counsel's motion *in limine* to admit the Podster IDIs filed on July 14, Dkt. No. 107, Commission IDIs are reliable, as they are official, legally-authorized public records of CPSC Field staff investigations that include official records and witness statements. Generally, however, "questions relating to the bases and sources of an expert's opinion affect the weight to be assigned to that opinion rather than its admissibility." *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 422 (5th Cir. 1987). Here, as Leachco is aware, Complaint Counsel intends to introduce the three IDIs documenting each fatal

[redacted]

incident at the hearing, which will allow the Court to independently evaluate the reliability of the facts underlying the expert's opinions.

CONCLUSION

For the foregoing reasons, Complaint Counsel respectfully requests that the Presiding Officer deny both Leachco's motion *in limine* and *Daubert* motion filed on July 14, 2023.

Dated this 24th day of July, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2023, I served Complaint Counsel's Opposition to Leachco's Motion *in Limine* and *Daubert* Motion on all parties and participants of record in these proceedings as follows:

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EXHIBITS 1-3

[Redacted in their entirety]