UNITED STATES OF AMERICA CONSUMER PRODUCT SAFETY COMMISSION

IN THE MATTER OF

CPSC Docket No. 22-1

LEACHCO, INC.

HON. MICHAEL G. YOUNG PRESIDING OFFICER

MEMORANDUM IN SUPPORT OF

LEACHCO, INC.'S MOTION TO EXCLUDE THE EXPERT TESTIMONY

PROFFERED BY THE CONSUMER PRODUCT SAFETY COMMISSION

INTRODUCTION

The Commission filed an administrative complaint alleging that Leachco's infant lounger—the Podster—presents a "substantial product hazard" under 15 U.S.C. § 2064(a)(2). To prevail, the Commission must prove that the Podster has a "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 loosely alleges that the Podster's design is defective based on hypothetical contingencies that "may" or "could" arise. For example, the Commission alleges that the Poster's design "may lead to" bedsharing and that it "facilitates movement off the Podster, which can result in an infant's nose and mouth being obstructed by another object in the infant's environment, such as soft bedding." Compl., ¶50(d), (e) (emphasis added).

But the Commission's key allegation is that "it is foreseeable" that the Podster will be misused. For example, the Commission alleges that caregivers "may trust that the products are safe places to leave infants" or "may" leave a sleeping infant in a

Podster; consumers "who are traveling or who are dealing with significant financial hardship may be more likely to" allow an infant to sleep in a Podster; and unsupervised infants "can" roll or move off the Podster. Compl., \P 920(a), (b), (d), 21. The Commission asserts that the design of the Podster is defective because, *e.g.*, it allegedly "facilitates" an infant's movement on the Podster, which purportedly "enhance[es]" some undefined and indeterminate "risk that the infant's nose and mouth will be obstructed" by the Podster or by another object such as soft bedding. *Id.* \P 927–28. The Commission also claims the Podster is defective because it "may be attractive to caregivers who wish to bedshare with an infant." *Id.* \P 32; *see also id.* \P 33. Thus, the Commission alleges that the Podster poses a "substantial risk of injury" because of the (allegedly) foreseeable misuses. *Id.* \P 938–41.

To support its claim, the Commission offers the purported expert testimony of Erin Mannen, Umakanth Katwa, and Celestine Kish. As explained below, the Court should grant Leachco's Motion and—

- I. Exclude the testimony of Dr. Mannen, Dr. Katwa, and Ms. Kish because the testimony is based on factual information that was not disclosed during fact discovery.
- II. Exclude the testimony of Dr. Katwa and Ms. Kish on Leachco's allegedly defective warnings as unhelpful and irrelevant.
- II. Exclude Dr. Mannen's proffered testimony because (A) she failed to disclose information and data underlying her report and (B) her testimony is unreliable and irrelevant.

- 2 -

¹ Leachco has filed an Appendix with the exhibits from this Motion and from Leachco's Motion *in Limine*. The Exhibit numbers are the same in both briefs. A copy of Dr. Katwa's report is attached to the Appendix as Ex. 1; a copy of Ms. Kish's report (without its attachments) is attached as Ex. 2; and a copy of Dr. Mannen's Report, along with excerpts from its attachments, is attached as Exhibit 3.

- III. Exclude Dr. Katwa's testimony on matters outside his proffered expertise.
- IV. Exclude the attempts by Dr. Katwa and Ms. Kish to introduce fact testimony through expert reports.

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 witnesses.

STANDARD OF ADMISSIBILITY

The admission of expert testimony is an exception from the norm that all evidence must be based on first-hand knowledge. Because of the unique nature of this testimony, courts must ensure the testimony's reliability and relevance. Judges thus have a "gatekeeping" function to ensure that a proposed expert's testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms.*, *Inc.*, 509 U.S. 579, 597 (1993). And judges must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, *Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

Rule 702 of the Federal Rules of Evidence requires that a proffered witness be "qualified as an expert by knowledge, skill, experience, training, or education." Even if a witness is qualified, her opinion may be admitted only if:

² See 16 CFR 1025.43(a) ("Unless otherwise provided by statute or these rules, the Federal Rules of Evidence shall apply to all proceedings held pursuant to these rules.").

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Id. In other words, the witness must be qualified, the testimony must help the trier of fact, and the testimony must be reliable.

The proponent of an expert witness bears the burden by a preponderance of the evidence showing that a witness's testimony meets the standards of Rule 702. See Daubert, 509 U.S. at 592 n.10; Sardis v. Overhead Door Corp., 10 F.4th 268, 283–84 (4th Cir. 2021); Krik v. Exxon Mobil Corp., 870 F.3d 669, 673 (7th Cir. 2017); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1306 (11th Cir. 1999).

ARGUMENT

- I. THE COURT SHOULD EXCLUDE THE TESTIMONY OF DR. MANNEN, DR. KATWA, AND MS. KISH BECAUSE THEIR TESTIMONY IS BASED ON EVIDENCE THAT WAS NOT DISCLOSED DURING FACT DISCOVERY
 - A. The Commission's proffered experts relied on information that was not produced during fact discovery

As set forth in detail in Leachco's Motion in Limine, during fact discovery,

Leachco asked	
	.3 The Commission
	"4 But the Commission

³ See Ex. 4, Leachco ROG No. 36; Ex. 5, Leachco RFP No. 50.

⁴ Ex. 6, CPSC First Supp. Resp. to ROG No. 36.

⁵ The Commission
.7
But the Commission's experts See Ex. 2,
Kish Report at 71 ¶151
; Ex. 3, Mannen Report at 13
; Ex. 1, Katwa Report at 5, 17.
Further, Dr. Mannen's report
See Ex. 3, Mannen Report at 62–64; id ., Ex. B (2019 study) at 4; id .,
Ex. C (2022 study) at 13. In her report here,
Mannen Report at 62–63.
⁵ <i>Id</i> . ⁶ Ex. 7 CPSC Resp. RFP No. 50.
Ex. 7 CFSC Resp. RFF No. 50.

B. Because the Commission's proffered experts relied on information not produced during fact discovery, the Court should exclude their testimony

For an expert's opinion to be relevant, it must assist "the trier of fact to understand the evidence or to determine a fact in issue." See Fed. R. Evid. 702(a). "In assessing whether the proffered expert testimony 'will assist the trier of fact' in resolving this issue," courts "must look to the governing substantive standard" Daubert, 43 F.3d at 1320. "Clearly, expert testimony does not 'help' if it is unrelated to facts at issue." Wright & Miller § 6265.2 (citations omitted).

Here, the Commission provided documents and samples to its experts, requested that the experts review them, and then the expert relied on those documents and samples. The Commission's proffered experts' reliance on evidence produced outside of discovery is improper because experts are "in effect locked-in to the factual record as of the time fact discovery closed." *Apple Inc. v. Samsung Elec. Co.*, No. 11-CV-01846, 2012 WL 3155574, at *5 (N.D. Cal. Aug. 2, 2012). Indeed, "data for an expert report should be gathered during fact discovery and . . . the extended deadline for the expert report is provided to give the expert time to thoroughly analyze the collected data." *Henry v. Quicken Loans Inc.*, No. 04-40346, 2008 WL 4735228, at *6 (E.D. Mich. Oct. 15, 2008); *see also ParkerVision, Inc., v. Qualcomm Inc.*, No. 3:11-cv-719-J-37-TEM, 2013 WL 3771226, at *4 (M.D. Fla. July 17, 2013) ("[T]he expert discovery period . . . does not provide an extended period of document discovery related to the disclosed experts.").

Courts thus routinely exclude expert reports when a party fails to disclose factual information during fact discovery. See R.D. v. Shohola, Inc., No. 3:16-CV-01056, 2019 WL 6211243, at *2 (M.D. Pa. Nov. 20, 2019); New Jersey Physicians United Reciprocal Exchange v. Boynton & Boynton, Inc., No. 12-5610 (PGS), 2017 WL 3624239, at *13 (D.N.J. Aug. 23, 2017) (striking plaintiff's expert report containing information not disclosed during fact discovery); Zurich Am. Ins. Co. v. Hardin, No. 8:14-CV-775-T-23AAS, 2020 WL 1150981, at *3 (M.D. Fla. Mar. 10, 2020); Bizrocket.com, Inc. v. Interland, Inc., No. 04-60706-CIV, 2005 WL 6745904, at *1 (S.D. Fla. Aug. 24, 2005); Gore v. 3M Co., No. 5:16-CV-716-BR, 2017 WL 5076021, at *2 (E.D.N.C. Nov. 3, 2017) ("[F]acts upon which experts may base their opinions . . . are distinct from the expert opinions themselves" and are "subject to the . . . fact discovery deadline."); DR Distributors, LLC v. 21 Century Smoking, Inc., No. 12 CV 50324, 2021 WL 185082, at *5 (N.D. Ill. Jan. 19, 2021); Bridge Aina Le'a, LLC v. Hawaii Land Use Comm'n, No. CV 11-00414 SOM-KJM, 2017 WL 5617463, at *1 (D. Haw. Nov. 21, 2017).

The Commission cannot "withh[o]ld . . . information that bears on [opposing party's] case while simultaneously providing that same information to its own expert." *Brown v. Wal-Mart Store, Inc.*, No 09-CV-02229-EJD, 2018 WL 2011935, at *5 (N.D. Cal. Apr. 27, 2018). "By producing" documents "after the close of fact discovery" the Commission "prevent[ed] [Leachco] from conducting further fact discovery related to that information and from incorporating those findings into [Leachco's] opening expert report." *Id.* And "[t]he only way to restore both parties to equal footing," is to "exclude" the information and "strik[e] . . . the related expert report." *Id.*

When experts do not have "an opportunity to review the withheld documents before forming their opinions," and a party cannot "question witnesses about the withheld documents," prejudice occurs. Zurich Am. Ins. Co. v. Hardin, No. 8:14-cv-775-T-23AAS, 2020 WL 1150981, at *2 (M.D. Fla. Mar. 10, 2020). This is true even when parties have rebuttal reports—something that Leachco does not have here. Id. at *3. Thus, Leachco faces even more prejudice than in a typical case. See Aetna Inc. v. Mednax, Inc., No. 18-2217, 2021 WL 949454, at *6 (Mar. 12, 2021) (prejudice not cured by a rebuttal report when "fact discovery has long since closed" because "any [rebuttal] report necessarily would rely on an artificially limited record"). In Zurich, the Court excluded documents and an expert opinion based on documents produced after the close of discovery—just as here. 2020 WL 1150981, at *3.

Nor may parties ignore fact-discovery obligations simply because they plan to make later disclosure during expert discovery. *MLC Intellectual Prop. LLC v. Micron Tech., Inc.,* 10 F.4th 1358 (Fed. Cir. 2021). In *MLC,* a party "argue[d] that it was not required to disclose these specific facts and documents supporting its damages theory during fact discovery because it ultimately disclosed them during expert discovery." *Id.* at 1369. Like the Commission here, the party in *MLC* argued that "it provided adequate responses to" interrogatories and "that anything more would have required it to disclose material designated for expert discovery." *Id.* Of course, a party need not "disclose its expert *opinions* during fact discovery," but it must disclose the evidence that an expert would rely on. *Id.* at 1371.

The Court in *MCL* therefore rejected the argument that a party "need not disclose factual underpinnings and evidence underlying" its legal theory "prior to expert discovery." *Id.* at 1372 (emphasis added); see also Vera v. Berkshire Life Ins. Co., No. 19-61360-CIV-DIMITROULEAS/SNOW, 2020 WL 8184335 (S.D. Fla. Dec. 24, 2020) (precluding party from "relying on the testimony" of experts based on documents not turned over in fact discovery).

* * *

The Commission provided evidence to its experts that it withheld from Leachco during fact discovery. At this late hour, this Court should not allow the Commission to change its theory of the case and add fact evidence.

This Court issued a stark warning to the parties that they would be precluded from using withheld discovery:



See also 8B Wright & Miller § 2289.1 (explaining that sanction prohibiting use of certain matters as evidence "applies not only at trial, but also with respect to any motion, such as a motion for summary judgment, or at a hearing.") (footnote omitted).

Therefore, the expert reports proffered by the Commission must be excluded.

⁸ Ex. 11, Feb. 24, 2023 Hearing Tr., 33:14-34:5.

II. EXPERT TESTIMONY ON THE ALLEGED DEFICIENCIES OF THE PODSTER'S WARN-INGS SHOULD BE EXCLUDED

Here, the Commission alleges a single claim: that it is foreseeable that people will misuse the Podster—despite Leachco's warnings. The Commission thus did not allege that the Podster's warnings and instructions were defective or inadequate.⁹

See Katwa Report at 29–30.

See Kish Report at 7–56. But because the Commission's claim does not involve an alleged defective or inadequate warning, testimony on that issue cannot possibly assist the trier of fact. See Kempner Mobile Electronics, Inc. v. Southwestern Bell Mobile Systems, 428 F.3d 706, 713 (7th Cir. 2005) (excluding expert testimony on fraud damages as irrelevant to theory of liability in fraud action); U.S. v. Cantrell, 999 F.2d 1290, 1292 (8th Cir. 1993) (affirming, in embezzlement action, exclusion of expert testimony on a union's purported authorization of defendant's actions because authorization was not an essential element of the case); Grayson v. No Labels, Inc., 601 F. Supp. 3d 1251 (M.D. Fla. 2022) (excluding expert testimony concerning compensatory damages when plaintiff did not have compensable damages); H.M. ex rel. B.M. v. Haddon Heights Bd. of Educ., 822 F. Supp. 2d 439 (D.N.J. 2011) (excluding portions of expert report related to claims that were beyond the statute of limitations).

⁹ Leachco has separately filed a Motion *in Limine* to exclude all documents and testimony concerning the alleged defects in the Podster's warnings.

Nor can the Commission attempt to "back-door" evidence related to Leachco's warnings through expert testimony. See Wright & Miller § 6265.2 ("[E]xpert opinion fails to help if it merely amounts to testimony about first-hand factual observations that are couched in the form of expert opinion.") (citation omitted).

* * *

The Commission did not allege that the Podster had a warnings defect, it repeatedly represented that its claim was not based on defective warnings, and it refused to produce documents and information related to Leachco's allegedly deficient warnings. The Commission should not be allowed to change its theory of the case at this late hour. Accordingly, the Court should exclude all expert testimony from Dr. Katwa and Ms. Kish concerning the alleged defects of the Podster's warnings.

III. Dr. Mannen's proffered testimony should be excluded for failure to provide all facts known to her

In *Daubert*, the Supreme Court made it clear that a judge must act as a "gate-keeper" to ensure that a proposed expert's testimony "both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597. Therefore, this Court must be satisfied that the proffered testimony is "based on sufficient facts or data," that the testimony is "the product of reliable principles and methods," and that the witness has "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d). The Court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, 526 U.S. at 152.

A. Dr. Mannen failed to disclose information and data underlying her report

According to the Commission's Rules of Practice for Adjudicative Proceedings,
parties are entitled to discover the "facts known" and opinions held by testifying ex-
perts. 16 C.F.R. 1025.31(d). See also Fed. R. Civ. P. 26 (requiring disclosure of the
"facts or data considered by the witness in forming" her opinions). Mannen
As a result, her current opinions—which are
based on those missing facts—should be excluded.
Dr. Mannen
See Ex. 3, Mannen Report at 8–11.
See id. at 11–13, 16.
As noted above,
$See~{ m Ex.}$
3, Mannen Report, Ex. B (2019 study) at 4; id ., Ex. C (2022 study) at 13. In her report
here, Mannen
Mannen Report
at 62–63.

As a result, Dr. Mannen's report should be excluded. When "a party fails to provide information" required by Rule 26, "the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or harmless." Fed. R. Civ. P. 37(c)(1). Additionally, Federal Rule of Evidence 702 requires the Court to act as a gatekeeper and preclude expert testimony that—because of an expert's failure to meet the disclosure requirements of FRCP 26—is unreliable. *See Laux v. Mentor Worldwide, LLC*, 295 F. Supp. 3d 1094, 1103 (C.D. Cal. 2017).

Here, as just noted, the Commission's failure to provide all data on which Mannen relied to form her opinions cannot be justified at all, and the failure is anything but harmless. Fed. R. Civ. P. 37(c)(1).

But, as Leachco fully explains in its separate Motion in Limine,

 $^{^{\}rm 10}$ Ex. 7, CPSC's Resp. to Leachco's 1st RFPs No. 28.

in Limine at 2-3.

Now, Dr. Mannen's report

This is improper. The Commission cannot use other infant products as both a shield to withhold discovery (claiming other products are irrelevant) and a sword to prove its case (using them as evidence against the Podster).

* * *

Therefore, even if Dr. Mannen's report should not be excluded entirely for the Commission's failure to produce evidence during fact discovery (see Section I, above), Dr. Mannen's report should be excluded for the failure to disclose the information required by 16 C.F.R. 1025.31(d) and FRCP 26. See Laux, 295 F. Supp. 3d at 1102–03.

B. Dr. Mannen's testimony is unreliable and irrelevant

Dr. Mannen's testimony should be precluded even if the Court excuses her failure to follow the disclosure requirements of 16 C.F.R. 1025.31(d) and FRCP 26

These documents provide only anecdotal information—they are not reliable scientific evidence. See, e.g., Wells v. SmithKline Beecham Corp., 601 F.3d 375, 380–81 (5th Cir. 2010) (finding testimony based on "anecdotal evidence" did not meet threshold for admission of expert testimony under Daubert standard); McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1250

 $^{^{11}}$ See Ex. 6, CPSC's Resp. to Leachco's 1st ROGs No. 21; see id. Nos. 23, 25, 27, 28, 29, 30, 31, 33, 34, 38 (same).

(11th Cir. 2005) ("anecdotal reports" about adverse events are "one of the least reliable sources to justify opinions about both general and individual causation"); Casey v. Ohio Medical Prods., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (same); see also In re Diet Drugs, No. MDL 1203, 2001 WL 454586, *15 (E.D. Pa. Feb. 1, 2001) (incident reports, which contain anecdotal information based on exposure to a product and alleged injury, are "universally recognized as insufficient and unreliable evidence of causation").

* * *

In sum, Dr. Mannen failed to disclose all facts she knew and relied on in her expert report. Her report, therefore, is based on unreliable evidence that does not meet the threshold for admission of expert testimony. For these reasons, this Court should exclude her testimony.

IV. DR. KATWA'S PROFFERED TESTIMONY ON MATTERS OUTSIDE HIS PROFFERED EXPERTISE SHOULD BE EXCLUDED

A proffered expert witness must have specialized knowledge on matters relevant to the case. Kumho Tire Co., 526 U.S. at 156; Tanner v. Westbrook, 174 F.3d 542, 548 (5th Cir. 1999). Therefore, even if a witness has some special knowledge or experience, the "qualification to testify as an expert also requires that the area of the witness's competence matches the subject matter of the witness's testimony." Bryant v. 3M Co., 78 F. Supp. 3d 626, 632 (S.D. Miss. 2015) (quoting Wright & Miller § 6265); see also Daubert, 508 U.S. at 592; (to be admissible, an expert's opinion must have a "reliable basis in the knowledge and experience of his discipline") (emphasis added). Thus, opinions on issues outside an expert's area of expertise lack "the requisite

scientific knowledge for his testimony to be helpful to the" trier of fact—and those opinions should be excluded. *Porter v. Whitehall Labs.*, *Inc.*, 9 F.3d 607, 615 (7th Cir. 1993).

Katwa Report at 5.
77 To A + 14 10 19
<i>Id.</i> , Ex. A at 14–16. ¹²
Ex. 1, Katwa Report at 17.
Id.
12 See id .

Id.*id*. at 18–26. See Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty."). Similarly, See Ex. 1, Katwa Report at 29–30.13 See, e.g., Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 970 (10th Cir. 2001) ("[M]erely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue.") (holding orthopedic surgeon with expertise in oncology not qualified to render an opinion on ade-

 13 Leachco has filed a Motion *in Limine* to exclude the introduction of any evidence related to the Podster's warnings or instructions.

quacy of manufacturer's warning).

V. EXPERT "FACT" EVIDENCE SHOULD BE EXCLUDED

The Commission's proffered experts all attempt to make findings of fact that
are an improper subject for expert testimony. For example,
Cas Ev. 1. Vature Danaut at 9C 90
See Ex. 1, Katwa Report at 26–29.
Id. at
26.
Id.
These attempts to present factual statements are improper.
Evidence of "exactly what happened" is "not a subject on which [the Commis-
sion's] experts have any expertise—or any other basis for knowledge—so their testi-
mony cannot fill [an] evidentiary gap." See Stephens v. Union Pac. R.R. Co., 935 F.3d
852, 857 (9th Cir. 2019).

* * *

The purported fact testimony about the three alleged incidents—Katwa Report at 26–29; Kish Report at 67–70; Mannen Report at 59–61—should be excluded.

CONCLUSION

This Court should grant Leachco's Motion and—

- I. Exclude the testimony of Dr. Mannen, Dr. Katwa, and Ms. Kish because the testimony is based on factual information that was not disclosed during fact discovery.
- II. Exclude the testimony of Dr. Katwa and Ms. Kish on Leachco's allegedly defective warnings as unhelpful and irrelevant.
- II. Exclude Dr. Mannen's proffered testimony because (A) she failed to disclose information and data underlying her report and (B) her testimony is unreliable and irrelevant.
- III. Exclude Dr. Katwa's testimony on matters outside his proffered expertise.
- IV. Exclude the attempts by Dr. Katwa and Ms. Kish to introduce fact testimony through expert reports.

A proposed order is attached.

DATED: July 14, 2023.

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CERTIFICATE OF SERVICE

I hereby certify that on July 14, 2023, I served, by electronic mail, the foregoing upon all parties and participants of record:

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UNITED STATES OF AMERICA CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of Leachco, Inc.,	CPSC DOCKET No. 22-1			
[PROPOSED] OR RESPONDENT LEACHCO, INC.'S MOTION PROFFERED BY THE CONSUMER 1	TO EXCLUDE THE EXPERT TESTIMONY			
Now before the Court is Respondent	Leachco, Inc.'s Motion to Exclude the Ex			
pert Testimony Proffered by the Consumer	Product Safety Commission. Having con			
sidered the Motion and finding good cause	therefor, IT IS HEREBY:			
ORDERED that Respondent Leachco's	s Motion to Exclude the Expert Testimon			
Proffered by the Consumer Product Safety Commission. Having considered the Mo				
tion is GRANTED; and further				
ORDERED that Complaint Counsel is precluded from introducing at the hear				
ing the proffered expert testimony of Dr. Mannen, Dr. Katwa, and Ms. Kish.				
ORDERED that a copy of this Order a	and accompanying Memorandum Opinior			
shall be entered on the docket and proceedi	ngs before the Presiding Officer are ter-			
minated.				
Dated:	Hon. Michael G. Young			
	Administrative Law Judge			