



## I. BACKGROUND

The factual background to this case has been laid out in previous orders. *See, e.g.*, Order Denying Defs.’ Mot. to Dismiss 1–2, ECF No. 326. In support of their allegations, Plaintiffs designated six experts to testify at trial. *See* ECF No. 106. On January 22, 2015, Defendants moved to strike the Rule 26 Expert Reports and testimony of four of those experts: 1) Louis Cantilena, M.D. (“Dr. Cantilena”); 2) Mahmoud ElSohly, Ph.D. (“Dr. ElSohly”); 3) Edward Mills, Ph.D. (“Dr. Mills”); and 4) Daniel Rusyniak, M.D. (“Dr. Rusyniak”). *See* ECF Nos. 184–187. On January 26, 2015, the matter was referred to Magistrate Judge Anne T. Berton pursuant to 28 U.S.C. § 636(b) and Appendix C of the Local Court Rules. (ECF No. 188). Plaintiffs filed a Response (“Plaintiffs’ Omnibus Response”) (ECF No. 200) on February 10, 2015. Defendants subsequently filed four Individual Replies (ECF Nos. 213, 219, 220, 221) and an Omnibus Reply (ECF No. 218) on March 6, 2015, and March 10, 2015. On April 27, 2015, and April 28, 2015, Magistrate Judge Anne T. Berton held a hearing pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *See* Order 1–3, ECF No. 235; *see also* ECF No. 321. On July 24, 2015, the parties filed a Joint Notice of Second Supplemental Reports. *See* ECF Nos. 327–1, 327–22.

On July 27, 2015, Magistrate Judge Anne T. Berton issued a seventy–two page Order granting Defendants’ Motion to Strike Dr. Cantilena, Dr. Mills, and Dr. Rusyniak and denying Defendants’ Motion to Strike Dr. ElSohly. Plaintiffs timely filed their Objections.

## II. ANALYSIS

### A. *Standard of Review*

Pursuant to 28 U.S.C. § 636(b)(1)(A), a district court judge may designate a magistrate judge, to hear and determine nondispositive pretrial matters pending before the court. *See*

*Castillo v. Frank*, 70 F.3d 382, 385 and n.6 (5th Cir. 1995); *Smith v. Smith*, 154 F.R.D. 661, 665 (N.D. Tex. 1994). The magistrate judge has broad discretion in the resolution of any such nondispositive matter. See *Credeur v. York Claim Serv.*, No. 13–1367, 2013 WL 5935477 at \*3 (W.D. La. Nov. 4, 2013) (citing Fed. R. Civ. P. 72(a)). After timely objection, a district court will only reverse or modify a magistrate judge’s order in a nondispositive matter “that is clearly erroneous or is contrary to law.” Fed. R. Civ. P. 72(a); *Castillo*, 70 F.3d at 385.

The clearly erroneous standard is applied to a magistrate judge’s factual findings. See *Lahr v. Fulbright & Jaworski, L.L.P.*, 164 F.R.D. 204, 208 (N.D. Tex. 1996) (quoting *Smith*, 154 F.R.D. at 665. “The district court may not disturb a factual finding of the magistrate judge ‘unless, although there is evidence to support it, the reviewing court is left with the definite and firm conviction that a mistake has been committed.’” *Id.* (quoting *Smith*, 154 F.R.D. at 665).

When a party objects to a magistrate judge’s order on the ground that it is contrary to law, the party must demonstrate that the magistrate judge erred in some respect in her legal conclusions. See *Smith*, 154 F.R.D. at 665 (quoting *Resolution Trust Corp. v. Sands*, 151 F.R.D. 616, 619 (N.D. Tex. 1993)). The magistrate judge’s legal conclusions are freely reviewable by the district judge, who applies a *de novo* standard and reverses if the magistrate judge erred in some respect in her legal conclusions. See *id.*

Where a magistrate judge has properly applied the law to fact findings that are not clearly erroneous, “a vast area of choice” exists in which the magistrate judge’s decisions are discretionary and the ruling may only be reversed for abuse of discretion, *id.* (quoting *In re REPH Acquisition Co.*, 134 B.R. 194, 202–03 (N.D. Tex. 1991)), such as when the district court “has a definite and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors.” *Dell Computer Corp. v.*

*Rodriguez*, 390 F.3d 377, 385 n.14 (5th Cir. 2004) (citation omitted); *see also Bollore S.A. v. Imp. Warehouse, Inc.*, 448 F.3d 317, 321 (5th Cir. 2006) (stating that it is an abuse of discretion for a judge to rule “in an unreasonable or arbitrary manner . . . without reference to any guiding rules and principles”).

The party objecting to the magistrate judge’s order must show how it is reversible under the applicable standard of review. *See Benton v. U.S. E.P.A.*, 3:06–CV–1591–D, 2012 WL 1037454, at \*1 (N.D. Tex. Mar. 28, 2012); *see also Jefferson–Pilot Life Ins. Co. v. Bellows*, No. 3:02–CV–1992, 2003 WL 21501904, at \*1 (N.D. Tex. June 24, 2003) (“When a party appeals a magistrate judge’s order, he must demonstrate how the order is reversible under the applicable standard of review—*de novo* for error of law, clear error for fact findings, or abuse of discretion for discretionary matters.”). “This means that, at a minimum, the party must identify the ruling being challenged, specify the standard of review, and explain why the decision in question is reversible under that standard.” *Librado v. M.S. Carriers, Inc.*, No. CIV.A. 3:02–CV–2095–D, 2004 WL 583602, at \*1 (N.D. Tex. Mar. 23, 2004). Here, Plaintiffs argue that the applicable standard of review is *de novo*. *See* Objections 1–2. Defendants contend that abuse of discretion is the proper standard. *See* Resp. to Objections 4–5.

Plaintiffs’ main argument is that the United States Supreme Court has held that the “admissibility of expert testimony is not an issue of fact.” Objections 2 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997)). They therefore conclude that “admissibility of testimony pursuant to [Federal Rule of Evidence] 702 is a conclusion of law.” *Id.* at 1. However, as noted by the Supreme Court, the standard of review is abuse of discretion. *See Joiner*, 522 U.S. at 143 (“[T]he question of admissibility of expert testimony is not such an issue of fact, and is reviewable under the abuse-of-discretion standard.”).

In fact, the Fifth Circuit applies the abuse of discretion standard when reviewing both a district court and magistrate court's admission or exclusion of expert testimony. *See Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 274 (5th Cir. 1998) (reviewing a district judge's decision to exclude expert testimony under the abuse of discretion standard); *United States v. Anderson*, 933 F.2d 1261, 1267–68 (5th Cir. 1991) (opining that a magistrate judge's decision to exclude evidence at trial is subject to a review for abuse of discretion); *Dart v. Kitchens Bros. Mfg. Co.*, 253 F. App'x 395, 397 (5th Cir. 2007) (reviewing a magistrate judge's decision to exclude expert testimony under the abuse of discretion standard); *see also United States v. Gonzales*, No. SA–10–CR–119–XR, 2010 WL 4736316, at \*5 (W.D. Tex. Nov. 16, 2010) (“A Magistrate Judge's decision to exclude evidence at trial is subject to a review for abuse of discretion.”), *aff'd* 449 F. App'x 392 (5th Cir. 2011). Plaintiffs argue, without support, that a “less deferential standard of review applies” to decisions of magistrate judges reviewed by district judges. *See* Objections 2 n.2. Without a more compelling argument, the Court is unable to agree. Accordingly, the Court will apply the abuse of discretion standard in its review of Magistrate Judge Berton's Order.

### ***B. Applicable Law***

Although state law governs the substance of the case, whether an individual is qualified to testify as an expert is a question of federal law. *See Mathis v. Exxon Corp.*, 302 F.3d 448, 459–60 (5th Cir. 2002) (citing Fed. R. Evid. 104(a)). The Court has broad discretion in deciding whether or not to admit expert testimony. *See Johnson v. Arkema, Inc.*, 685 F.3d 452, 460 (5th Cir. 2012); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (*en banc*).

Federal Rule of Evidence 702 governs the admissibility of expert testimony. *See Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009). It provides that a witness “who is qualified as an

expert by knowledge, skill, experience, training, or education may testify in the form of an opinion.” Fed. R. Evid. 702. The expert’s testimony is admissible if:

(a) the expert's scientific, technical, or other specialized knowledge will assist 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.* The party seeking to introduce the expert witness “must demonstrate that the expert’s findings and conclusions are based on the scientific method, and, therefore, are reliable.” *See Moore*, 151 F.3d at 276.

Generally, “an expert is permitted wide latitude to offer opinions, including those not based on firsthand knowledge or observation.” *Daubert*, 509 U.S. at 592. Trial courts act as gatekeepers, ensuring that the expert testimony is relevant and reliable. *Id.* at 596–97. In that capacity, the Court has wide discretion to decide whether the testimony is reliable as well as “considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). While the Supreme Court has provided some guidance on how to determine an expert’s reliability under certain circumstances, it has acknowledged that “[t]oo much depends upon the particular circumstances of the particular case at issue” to set out rigid requirements to test reliability. *Id.* at 150. The Fifth Circuit has cautioned that trial courts “must resolve cases . . . on the basis of scientific knowledge that is currently available,” and only evidence that demonstrates a causal relationship between a product and an alleged injury can be admitted as relevant and reliable. *See Moore*, 151 F.3d at 274, 276; *see also Brumley v. Pfizer, Inc.*, 200 F.R.D. 596, 602 (S.D. Tex. 2001) (requiring evidence of causation and noting that “the lack of proof of a drug’s safety does not prove that it is dangerous”). However, “[v]igorous cross-examination,

presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

### ***C. Discussion***

Plaintiffs offer seven specific objections to the magistrate judge’s Order.<sup>1</sup> *See* Objections 6–15. The Court will determine the merit of each of these objections in turn. Plaintiffs also argue broadly that their experts’ opinions regarding whether DMAA<sup>2</sup> is capable of causing hyperthermia and death are based on considerable evidence and reliable methodologies. *See* Objections 2–6. The Court notes that many of Plaintiffs’ proffered arguments and evidence advance arguments that the magistrate judge already considered. *See* Objections 2–6. This is because Plaintiffs press their objections under the stringent *de novo* standard. Because the Court has already determined that the more deferential abuse of discretion standard applies, the Court’s mandate is not to reconsider the same evidence and arguments that the magistrate judge already weighed, but rather to see if the magistrate judge ruled “in an unreasonable or arbitrary manner . . . without reference to any guiding rules and principles.” *Bollore S.A.*, 448 F.3d at 321. The Court therefore limits itself to the specific objections to the Order raised by Plaintiffs.

#### **1. Objection 1: Whether the Magistrate Judge Considered Material Scientific Admissions from Defendants’ Experts on Both the Ultimate Causation Opinions As Well As The Mechanism of Action**

In her Order, Magistrate Judge Berton concluded that Plaintiffs’ proposed expert, Dr. Cantilena, made “too many analytical gaps in the causal chain” for Plaintiffs’ mechanism of

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<sup>1</sup> Plaintiffs actually offer eight objections. However, their seventh enumerated objection deals with Dr. Cantilena’s calculations related to the animal studies (e.g. Marsh and Coyle studies). Because the Court will consider the magistrate judge’s ruling regarding the reliability of Dr. Cantilena’s expert report as part of Plaintiffs’ other objections, the Court will not directly address this objection separately. *See* Objections 14–15.

<sup>2</sup> DMAA is shorthand for the compound 1,3-Dimethylamylamine.



action theory to be scientifically reliable. *See* Order 37. The magistrate judge cited to the testimony of Plaintiffs' experts to support her finding.

Dr. Cantilena admitted that he had not relied on any studies indicating that an increase in blood pressure related to an increase in cutaneous vasoconstriction in humans. (*See* Hr'g Tr. 108:20–23, Apr. 27, 2015 PM, ECF No. 323) . . . . [Dr. Rusyniak] “testified that ‘*none* of the human studies . . . were set up or designed to properly detect whether [DMAA] would *cause* hyperthermia” and that “he was not aware of any peer reviewed literature that identified a susceptible population with regard to DMAA and heat stroke and hyperthermia.”

(Order 37, 63–64) (emphasis in original).

Plaintiffs argue that “[c]ritical causation issues were conceded by Defense experts,” namely that “[t]he concession as to mechanism was ignored” by the magistrate judge. *See* Objection 6. Plaintiffs draw attention to deposition testimony by defense expert Dr. Joseph Rodricks and an internal report authored by Cy Wilson, a USPLab’s science consultant. *See* Objections 6–7. Plaintiffs argue that it was error to exclude from evidence the admissions of the opposing party’s expert.<sup>3</sup> *See* Objections 6.

Plaintiffs cite *Collins v. Wayne Corp.*, 621 F.2d 777, 781 (5th Cir. 1980), *superseded on other grounds by* Fed. R. Evid. 103(a), for this proposition. Plaintiffs, however, are conflating evidentiary proof to support their theory of causation with the reliability determination of their experts’ opinions under *Daubert*. The key issue here is whether the offered testimony by Plaintiffs’ experts is reliable. Nowhere in Plaintiffs’ experts’ reports do they cite reliance on Defendants’ experts as a basis for their opinions.<sup>4</sup>

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<sup>3</sup> Plaintiffs also argue that it was error for the magistrate judge to discount other studies that support Plaintiffs’ mechanism of action theory. *See* Objections 6. On the contrary, the magistrate judge considered the relevant studies and found that they were either unreliable or did not support Plaintiffs’ position. *See, e.g.*, Order 29–30, 42.

<sup>4</sup> Ironically, Dr. Rodricks formed some of his own opinions based in part on the Bloomer studies that the magistrate judge found to be insufficiently reliable. The reliability of the defense expert,



Moreover, at most the statement by a defense expert is an evidentiary admission, and not a judicial admission. *See Collins*, 621 F.2d at 782 (stating that the excluded expert’s deposition testimony “was not, of course, a binding judicial admission” and that if the testimony had been admitted, the party against whom it was offered “would have had an opportunity to explain why some of [their own expert’s] conclusions were not consistent with [their] position at trial.”). A judicial admission is an intentional waiver, “releasing the opponent from proof of fact.” *Martinez v. Bally’s La., Inc.*, 244 F.3d 474, 476 (5th Cir. 2001). In contrast, an evidentiary admission is “merely a statement of assertion or concession made for some independent purpose.” *Id.* at 476–77 (quoting *McNamara v. Miller*, 269 F.2d 511, 515 (D.C. Cir. 1959)). A party may attempt to contradict and explain an evidentiary admission, but a judicial admission is binding absent leave to withdraw it. *Id.* at 477 (citing *Keller v. United States*, 58 F.3d 1194, 1199 n.8 (7th Cir. 1995)). Because Defendants are clearly disputing the effects of DMAA compared to other other sympathomimetic alpha–agonist vasoconstrictors, or that it causes or contributes to hyperthermia or heat stroke, *see* Resp. to Objections 5 (emphasis in original omitted), it is clear that the statements made by Dr. Rodricks and Cy Wilson are not judicial admissions. The Court therefore overrules Plaintiffs’ first objection.

## **2. Objection 2: Whether the Magistrate Judge Improperly Considered Defense Argument and Cross–Examination as Evidence**

Plaintiffs also argue that the magistrate judge improperly adopted defense argument and cross–examination as evidence. Plaintiffs specifically point to the magistrate’s consideration of the Marsh dog studies. *See* Objections 7. Plaintiffs argue that “the Magistrate made an independent factual finding that the dog model was unreliable despite no evidence to the contrary

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however, is not before the Court. *See* Supporting Exs. to Doc. 196, Ex. OO, Rodricks Dep. at 24:4–20, ECF No. 197–36.

and despite a party admission, she supplanted her scientific opinion for that of an expert in pharmacology.” *See id.* at 7–8.

The issue here is not “whether animal studies can ever be a proper foundation for an expert’s opinion,” but rather “whether *these* experts’ opinions were sufficiently supported by the animal studies on which they purported to rely.” *Joiner*, 522 U.S. at 144 (emphasis in original). Magistrate Judge Berton determined that the conclusions of Plaintiffs’ experts based on studies of dogs were not reliable because Plaintiffs’ experts failed to account for differences between the dog studies and the circumstances at issue in this case, specifically the delivery mechanism and the dosage. *See* Order 43, 55 (stating that Dr. Cantilena, in his extrapolation from the dog studies to human effects, “ignored the fact that the Coyle study subjects were injected with epinephrine and that the dogs in Marsh were injected with epinephrine and DMAA, as compared to Decedent who took DMAA orally” and that Dr. Mills’ “opinion on dose–response fails to account for the different doses used in animals and humans.”)

She also noted that “Dr. Mills conceded that data from animal studies does not always extrapolate accurately to effects in humans.” *Id.* at 55.<sup>5</sup> Magistrate Judge Berton concluded that she was left with “Dr. Mills’ mere assurances that dogs are a good model to predict human effects” and found these assurances insufficient. *See id.* Likewise, she concluded that Dr. Cantilena “provided no support for his extrapolation from the dog data to human data other than his assurances that literature existed on the subject” and, stated that even assuming such literature does exist, he “freely admitted that he did not rely on that material to form his opinion.” *Id.* at 42–43.

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<sup>5</sup> Citing to Supporting Exs. to Doc. 196, Ex. LL, Dr. Mills Dep. 99:22-100:4, 101:11–102:2, ECF No. 197–33.

Under the applicable standard of review, the Court is not convinced that Magistrate Judge Berton committed a clear error of judgment in her conclusion. Because “studies of the effects of chemicals on animals must be carefully qualified in order to have explanatory potential for human beings” and Plaintiffs’ experts did not take the steps necessary to qualify the dog studies for human extrapolation based on the circumstances of this case, Magistrate Judge Berton properly found that the opinions derived from the dog studies were unreliable. *See Allen v. Penn. Eng’g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996). Plaintiffs’ second objection is overruled.

**3. Objection 3: Whether the Magistrate Judge Failed to Consider the Opinions as a Whole and Missed Numerous Bridges Between the Data and the Proffered Opinions**

Plaintiffs argue that “[t]here is no evidence that . . . Dr. Cantilena was not qualified to make the analysis [n]or that the analysis was flawed.” Objections 8. Plaintiffs cite out of circuit cases for the proposition that the “entire body of evidence relied on by the expert should be taken into consideration in evaluating the reliability of the opinion, and the court should refrain from an ‘atomistic’ approach that determines that each piece of evidence is insufficient, on its own, to support the expert’s conclusion.” *Id.* Plaintiffs conclude that “Dr. Cantilena’s calculations bridge the gap the Magistrate said existed in the class effect discussion by accounting for differences in route of administration, pharmacokinetics, potency, and by providing an established mechanism of action.” *Id.*

Plaintiffs primarily rely on an out-of-circuit court of appeals case, *Milward v. Acuity Specialty Prods. Group, Inc.*, 639 F.3d 11, 23 (1st Cir. 2011). The Court is not typically persuaded by outside courts when the Fifth Circuit Court of Appeals has generated a wide body of law to guide the Court’s rulings, but finds this case instructive nonetheless for the issue at hand. In *Milward*, the First Circuit reversed a trial court’s exclusion of an expert. The court of appeals determined that the trial court had improperly crossed over from gatekeeper to factfinder

in making its reliability assessment. *See id.* at 22. It based its conclusion in part on its finding that the trial “court’s analysis repeatedly challenged the factual underpinnings of [the expert’s] opinion, and took sides on questions that are currently the focus of extensive scientific research and debate—and on which reasonable scientists can clearly disagree.” *Id.* It further warned trial courts that proponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered “to determine which of several competing scientific theories has the best provenance.” *Id.* at 15 (citation omitted). “[T]he fact that another explanation might be right is not a sufficient basis for excluding [the expert]’s testimony.” *Id.* at 22.

However, the *Milward* court also cautioned that the proponent of expert evidence must show that “the expert’s conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.” *Id.* at 15 (citing *Daubert*, 509 U.S. at 85). “Trial judges may evaluate the data offered to support an expert’s bottom–line opinions to determine if that data provides adequate support to mark the expert’s testimony as reliable.” *Id.* Here, Magistrate Judge Berton did not make a factual assessment of the weight of the experts’ opinions. Rather, she focused on the reliability of using the studies that underpinned Dr. Cantilena’s proffered opinion to “bridge the gap,” explaining that “Dr. Cantilena provides no indication that other experts in his field use similar methodologies to extrapolate between sympathomimetics and he pointed to no literature making these comparisons to validate his approach.” Order 41; *see also id.* at 43–44 (explaining that Dr. Cantilena failed to properly account how a difference in the epinephrine equivalence of Decedent’s DMAA blood levels impacted his conversions and calculations). Judge Berton took care to cite to Dr. Cantilena’s own testimony to support her conclusions. *See id.* In effect, she found that because the underlying studies were unreliable and

could not be used to support Dr. Cantilena's conclusions, she was left with nothing but the *ipse dixit* of the expert. Consequently, she determined that Dr. Cantilena was unreliable. *See Milward*, 639 F.3d at 22 (“There is an important difference between what is *unreliable* support and what a trier of fact may conclude is *insufficient* support for an expert's conclusion.”).

Because the Court cannot say that Magistrate Judge Berton acted in “an unreasonable or arbitrary manner,” Plaintiffs’ third objection is overruled.

#### **4. Objection 4: Whether the Magistrate Judge Erred in Holding that the Opinions at Issue Were Nothing More than Opinions of Class Effect**

Plaintiffs next claim that the magistrate judge misapplied “Fifth Circuit law as to ‘class effects’ . . . .” Objections 9. They contend that that they are not merely asserting a class effect, but also extrapolating effects for particular chemicals based on class comparisons to bridge the analytical gap. *See id.* at 10–11. Plaintiffs also assert that the magistrate judge erred in her assessment of the scientific reliability of the outliers in the studies. *See id.* at 11–12.

Plaintiffs again cite two out-of-circuit district courts for specific comparisons and attempts to distinguish the Fifth Circuit cases relied upon by the magistrate judge. *See id.* at 9. The Court remains more persuaded by the Fifth Circuit’s opinions.

The magistrate judge primarily relied on the Fifth Circuit’s holdings in *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375 (5th Cir. 2010), and *Huss v. Gayden*, 571 F.3d 442 (5th Cir. 2009). In *Wells*, the Fifth Circuit rejected expert testimony which attempted to analogize between drugs in the class of dopamine agonists and their ability to cause impulsive behaviors. *See Wells*, 601 F.3d at 377–80. Similarly, in *Huss*, the appellate court rejected the proposed expert’s class of chemical theory as to sympathomimetic drugs. *See Huss*, 571 F.3d at 458–59.

The Fifth Circuit subsequently relied on its previous holding in *Wells* to conclude that extrapolation is only admissible when there is evidence that the “leap from one chemical to another [is] reasonable and scientifically valid.” *See Arkema, Inc.*, 685 F.3d at 460 (quoting *Moore*, 151 F.3d at 279). When such evidence is lacking or when “there is simply too great an analytical gap between the data and the opinion proffered,” courts are “free to reject a theory based on extrapolation.” *Id.* at 460–61 (quoting *Joiner*, 522 U.S. at 146).

Here, the magistrate judge applied these principles to conclude that Plaintiffs’ experts’ opinions were unreliable. The magistrate judge noted that Plaintiffs’ own experts admitted that DMAA was structurally different from other class chemicals. *See* Order 59–60. Combined with an acknowledgement that DMAA’s class, sympathomimetics, could have dissimilar effects, this was sufficient to find the offered opinions unreliable, where Plaintiffs were unable to “bridge the analytical gap between the data and the opinion offered.” *Accord Joiner*, 522 U.S. at 146; Order 33. As recognized by the magistrate judge, Plaintiffs’ own expert acknowledged that “not all sympathomimetics have the same dose–response curve, effects on blood pressure, vasoconstriction, and body temperature, and that they are not absorbed at the same rate in the body.” Order 60. This led her to conclude that “Dr. Cantilena’s attempt to go from vasoconstriction and increased blood pressure to increased heat production, thereby causing harm to susceptible individuals, ultimately has too many analytical gaps in the causal chain.” Order 37; *see also id.* at 61 (“Dr. Rusyniak admitted that increased blood pressure does not necessarily correspond with an increase in body temperature.”). Similarly, when addressing the user of the study outliers, the magistrate judge found that there was no evidence to support Dr. Cantilena’s reliance on outliers because he could not cite any authority supporting his methodology under the circumstances of this case. *See* Order 39. She also noted that Dr.



Cantilena admitted the decedent had characteristics similar to the main study population as well as outliers and failed to account for those similarities as well as difference in dosages. *See id.* at 39–40.

Plaintiffs bear the burden to prove that their experts’ opinions are admissible. *See Huss*, 571 F.3d at 459 (“[A] plaintiff who insists that a drug, not another factor, caused the disease faces a high burden in proving general causation.”). The magistrate judge clearly outlined her reasoning and analysis as to why she rejected the class effects, mechanism of action, and outliers in the relevant studies and this Court cannot say she abused her discretion in reaching her conclusion. This objection is overruled.

**5. Objection 5: Whether the Magistrate Judge Improperly Discounted Plaintiffs’ Experts’ Opinions that DMAA Can Cause Hyperthermia to the General Public**

Plaintiffs’ next objection is that Magistrate Judge Berton should not have discounted their experts’ assertions that DMAA can cause harm to the general population. *See* Obj. 12–13. Plaintiffs argue that the magistrate judge “placed too much focus on the literal meaning of ‘general population,’” *id.* at 13, because “[g]eneral population does not mean all people. An expert does not have to opine that a drug *actually* causes harm in everyone only that it is capable of harming people in the general population.” *Id.* at 12.

As noted by Defendants, the magistrate judge rejected the conclusions of Plaintiffs’ experts because she found the underlying studies to be unreliable. *See* Order 62–63. She reached this conclusion in part because the researchers conducting the studies themselves observed that the sample size was too small to “‘generalize these findings to the population at large.’” Order 36. In addition, the magistrate judge relied on Plaintiffs’ own experts who



acknowledged that the available data was insufficient “to conclude that DMAA is safe or that DMAA causes harm because the sample sizes are too small.”<sup>6</sup> *Id.* at 36.

Because the magistrate judge found that Plaintiffs’ experts did not base their opinion on any study that reliably tested whether DMAA can cause hyperthermia in the general population, she properly determined that the experts failed to “reliably use scientific methods to reach [their] conclusions on a biologically plausible mechanism.” *See id.* at 37. Consequently, the magistrate judge did not abuse her discretion when she concluded that Plaintiffs’ experts’ opinions insufficiently supported the proposition that DMAA can cause hyperthermia in the general population. *See id.* at 36–37. This objection is overruled.

#### **6. Objection 6: Whether Dr. Cantilena’s Calculations Were Properly Excluded**

Plaintiffs argue that the magistrate judge committed error by

impos[ing] additional hurdles to admissibility, including proof that a study concludes the ultimate opinion that DMAA causes hyperthermia in the general population, that a study even though statistically significant needs some minimum sample size, that it is unreliable to use a study which does not reach a conclusion on the issue of ultimate causation, that statistical analysis is a prerequisite to using outliers despite the fact the methodology requires a clinical assessment, that an opinion is only reliable if created before litigation, and that only peer reviewed methodologies are reliable.

Objections 13. They insist that Magistrate Judge Berton went beyond her gatekeeping role and improperly “weighed the evidence.” *Id.* at 14.

However, for example, Magistrate Judge Berton did not hold that “an opinion is only reliable if created before litigation,” *see* Objections 13, but rather pointed out that expert

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<sup>6</sup> *See Order* at 36 (“Dr. Cantilena’s Rule 26 Expert Report opined that ‘no adequately powered study has ever been performed on DMAA to accurately assess the occurrence of uncommon or relatively rare adverse health outcomes in the general population.’”) (emphasis in original); *id.* at 50 (“Dr. Mills acknowledged Dr. O’Brien’s testimony that the Schilling study does not provide a large enough sample size to make a conclusion as to whether DMAA elevates body temperature.”); *id.* at 63 (“Dr. Rusyniak testified that the increase in temperature demonstrated in the Schilling study did not meet the definition of hyperthermia and that the study was not accurate because the sample size was too small.”).

opinions “based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions” are scientifically valid. Order 41 (quotations omitted).

Moreover, the magistrate judge focused on Plaintiffs’ experts’ methodology in making her reliability assessment and examined the circumstances of the studies as to their reliability, not their ultimate evidentiary weight. *See, e.g.*, Order 36–37. Plaintiffs’ experts’ decisions to rely on studies that reached contrary conclusions to those drawn by Plaintiffs’ experts and studies that lacked sufficient sample size to be considered reliable are flaws in methodology that led Plaintiffs’ experts to reach unreliable conclusions. *See Huss*, 571 F.3d at 459 (“It is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation had been proven.”).

It was a combination of all of the factors cited by Plaintiffs that led the magistrate judge to reach her ultimate conclusion. *See e.g., Newton v. Roche Labs., Inc.*, 243 F. Supp. 2d 672, 676 (W.D. Tex. 2002) (citing *Marcel v. Placid Oil*, 11 F.3d 563, 567 (5th Cir. 1994)) (stating that in considering reliability, the district court must consider the validity of the principles applied by the expert, the accuracy of the data relied upon by the expert, and the precision of the application of the principles to the relevant data). As a result, the magistrate judge did not impose any additional burdens on Plaintiffs’ experts. This objection is overruled.

#### **7. Objection 7: Whether the Magistrate Judge Ignored Peer–Reviewed Medical Literature**

Plaintiffs final objection is that Magistrate Judge Berton “ignored the [Department of Defense study] which concluded that DMAA is capable of causing hyperthermia and that

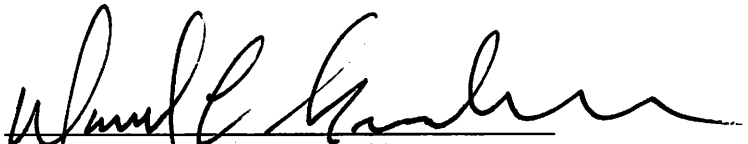
[Decedent's] death is consistent with his use of Jack3d.” Objections 15. Plaintiffs assert that the Department of Defense study “should have been considered as evidence that the methodologies and opinions of Plaintiffs’ experts were reliable and sound.” *Id.*

However, the magistrate judge did consider the Department of Defense study. *See* Order 29–30. Magistrate Judge Berton noted that the study found that “existing evidence does not conclusively establish that DMAA-containing substances are causally-associated with adverse events.” *Id.* at 30. The Court overrules this final objection.

#### IV. CONCLUSION

Accordingly, **IT IS HEREBY ORDERED** that Plaintiffs Leanne Sparling and Michael J. Sparling’s, on behalf of and as representatives for Michael L. Sparling, deceased, Objection to Magistrate Judge Anne T. Berton’s July 27, 2015, Order (ECF No. 338), is **OVERRULED**.

So **ORDERED** and **SIGNED** this 20<sup>th</sup> day of January, 2016.

  
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**DAVID C. QUADERRAMA**  
**UNITED STATES DISTRICT JUDGE**