

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
NORTHERN DIVISION
at ASHLAND

Civil Action No. 11-109-HRW

LLOYD McCARTY
and
BETH McCARTY,

PLAINTIFFS,

v.

MEMORANDUM OPINION AND ORDER

ARCH WOOD PROTECTION, INC., *et al.*,

DEFENDANTS.

This matter is before the Court upon the Report and Recommendation of United States Magistrate Judge Candace Smith pertaining to Defendants' Joint Motion to Exclude Testimony Regarding the Alleged Cause of Pulmonary Nodular Lymphoid Hyperplasia pursuant to Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.* [Docket No. 245], Plaintiffs' Motions to Exclude or Limit the Opinions and Testimony of Defendants' Experts Michael Koss, M.D. and Philip S. Guzelian, M.D. [Docket Nos. 254 and 255] and Defendants' Joint Motion for Summary Judgment Based on Plaintiffs' Failure to Prove General or Specific Causation [Docket No. 252].

I.

In a thorough and detailed Report and Recommendation, Magistrate Judge Smith concludes that Plaintiffs have not presented admissible evidence to meet their burden of proof that Mr. McCarty's exposure to CCA-treated wood caused the development of PNLH. However, Defendants have not established an absence of any genuine issue of material fact as to causation of Mr. McCarty's alleged non-PNLH health problems [Docket No. 295]. Therefore,

she recommends that Defendants' Joint Motion to Exclude Testimony Regarding the Alleged Cause of Pulmonary Nodular Lymphoid Hyperplasia pursuant to Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.* be sustained, Plaintiffs' Motions to Exclude or Limit the Opinions and Testimony of Defendants' Experts Michael Koss, M.D. and Philip S. Guzelian, M.D. be overruled as moot and Defendants' Joint Motion for Summary Judgment Based on Plaintiffs' Failure to Prove General or Specific Causation be sustained as to Mr. McCarty's PNLH and overruled as to his non-PNLH health problems.

Plaintiffs filed timely and particularized Objections to the Report and Recommendation [Docket No. 302]. First, Plaintiffs contend that Magistrate Judge Smith improperly concluded that Drs. Stark and Saggar did not meet the requirements of the *Best* differential diagnosis standard, even though they ruled out idiopathic causes and considered factors in addition to the differential diagnosis. Plaintiffs also maintain that Magistrate Judge Smith improperly excluded the opinions of Drs. Costa and Lantz, including the general opinions as to causation which are not dependent on a *Best* differential diagnosis.

II.

Plaintiffs argue that Magistrate Judge Smith erred in excluding testimony of Drs. Stark and Saggar because they allegedly ruled out idiopathic causes and considered factors in addition to the differential diagnosis. However, the testimony establishes that although these doctors considered and ruled out other diseases, they could not rule out an idiopathic cause, which accounts for all other known cases of PNLH. In addition, to the extent Plaintiffs argue these doctors took steps beyond a differential diagnosis, such steps require speculation to reach a conclusion that arsenic can cause PNLH.

Plaintiffs argue that Drs. Saggar and Stark offer steps far beyond those in *Best*, but fail to recognize that the expert in *Best* ruled out an idiopathic cause. In *Best*, the plaintiff suffered burns on his skin, irritation to his nasal passages and mouth, dizziness and shortness of breath immediately after the chemical in question splashed on his face. *Best v. Lowe's Home Centers*, 563 F.3d 171, 174 (6th Cir. 2009). *Best* completely lost his sense of smell. Dr. Moreno testified that loss of smell is caused by a virus, an accident, tumors or surgery of the brain, exposure to chemicals, some medications, and is sometimes idiopathic, meaning it occurs for unknown reasons. The Sixth Circuit approved Dr. Moreno's differential diagnosis because he confirmed *Best* was anosmic, reliably ruled in potential causes, including the chemical in question, and engaged in standard techniques to rule out alternate causes, including an idiopathic cause. *Id.* at 180-82. With respect to ruling out an idiopathic anosmia, the Sixth Circuit held Dr. Moreno adequately ruled out idiopathic anosmia by finding, based on his experience, that idiopathic anosmia would not appear over such a short period of time.

In this case, the experts could not rule out an idiopathic cause of Mr. McCarty's PNLH- which accounts for essentially every known case of PNLH. Nor do Drs. Saggar or Stark rely on literature that supports a causal connection between arsenic and PNLH. In fact, both admit the literature does not demonstrate a causal connection. Instead, the studies they reference at best link arsenic to causing lymphoid proliferation or having an effect on the immune system. However, the experts admit that there are many causes of lymphoid proliferation, and there is no evidence in Mr. McCarty's medical records that he had a disregulated immune system. Further, they admit they found no studies linking arsenic exposure to PNLH. Thus, while they considered Mr. McCarty's exposure to arsenic, his positive urine test for arsenic, the temporal connection

between exposure and the onset and cessation of his symptoms, there is simply too great an analytical gap between the data and their opinions that arsenic exposure caused Mr. McCarty's PNLH.

This case is more analogous to *Tamraz*, which, notably, Plaintiffs do not discuss in their Objections, wherein the Sixth Circuit held the trial court erred in permitting a welder's neurologist to present a speculative opinion that his exposure to the defendants' products triggered a manganese-induced Parkinsonism. *Tamraz v. Lincoln Electric Co.*, 620 F.3d 665, 674-76 (6th Cir. 2010). The Sixth Circuit found the expert's testimony could not be defended as an admissible differential diagnosis because his efforts to "rule in" manganese exposure as a possible cause or to "rule out" an idiopathic cause, which accounted for the vast majority of Parkinson's Disease cases, turned on speculation, not valid methodology. The Sixth Circuit has held that where an unknown idiopathic origin accounts for a vast majority of cases, it is "impossible to ignore and difficult to rule out." *Id.* Thus, to meet the reliability standard, the experts must provide some basis for ruling out an unknown idiopathic origin as the cause of Mr. McCarty's PNLH because all the experts agree that the medical and scientific community does not know why a given individual develops PNLH.

Therefore, while Plaintiffs argue Drs. Stark and Saggart ruled out other idiopathic causes, their testimony does not support that they ruled out an idiopathic cause, meaning the medical community does not know why a given individual has PNLH - its cause is simply unknown. While it is undisputed that these doctors considered other potential illnesses, they did not and could not rule out that the cause was idiopathic. The experts need not rule out all possible causes, but they must consider and exclude obvious causes, which in this case, as in *Tamraz*,

requires ruling out an idiopathic cause as it is what accounts for every other known case of PNLH. Thus, the experts' differential etiology is not reliable as they failed to rule out an idiopathic cause. Further, having no other data demonstrating arsenic can cause PNLH, the experts' opinions that it is the cause of Mr. McCarty's PNLH is simply too speculative to be deemed admissible scientific knowledge. As in *Tamraz*, the testimony of Drs. Stark and Saggari is not admissible expert testimony.

Plaintiffs also object to the analysis of Drs. Lantz's and Costa's opinions only as to their admissibility on general causation.¹ [Docket No. 302, at 9]. Plaintiffs explain that general causation is the inquiry into whether an exposure to a substance can cause a particular disease and can be proven via review of scientific and medical literature. (*Id.* at 10) (citing *In re Heparin Products Liab. Litig.*, 803 F. Supp. 712, 724 (N.D. Ohio 2011)). Plaintiffs further state that a general causation expert's testimony is not unreliable simply because it is based on non-epidemiological evidence, but note that when an expert relies on animal studies, they are required to explain how the studies can be reliably extrapolated to prove comparable human effects. (*Id.*).

Plaintiffs argue Drs. Lantz and Costa relied on a number of articles to support their

¹ To the extent Plaintiffs argue the Court was not required to undertake an extensive *Daubert* analysis on general causation because it is generally accepted that NLH is a lymphocytic proliferative disease of unknown origin and arsenic is a toxic known to cause lymphocytic proliferation, the argument lacks merit. [Docket No. 302, at 11] (citing *McClain v. Metabolife Internat'l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005)). *McClain* explains that where the medical community generally recognizes the chemical is both toxic and capable of causing the injury alleged, i.e. asbestos is known to cause asbestosis and mesothelioma, an extensive *Daubert* analysis is not required on general causation. *Id.* However, as the R&R explains in great detail, the experts agree that it is not generally accepted that arsenic is capable of causing PNLH. Instead, no one knows the cause of PNLH. Thus, the experts are required to offer reliable opinions that arsenic is capable of causing PNLH.

opinions of a plausible link between arsenic and NLH. They argue that “the error in the Report and Recommendation is that the distance between the known toxic immune/lymphoproliferative effect of arsenic and Dr. Costa’s general causation opinion on NLH may be a gap, but not a ‘leap’ requiring exclusion.” [Docket No. 302, at 11]. While the Objections note that Magistrate Judge Smith critiques selected articles to support a conclusion that the opinions are unreliable, the Plaintiffs do not explain why that critique is in error. Nor do Plaintiffs offer any explanation as to how the experts bridge the gap between knowing arsenic can cause lymphocytic proliferation or a compromised immune system and the conclusion that it can also cause PNLH. In fact, Dr. Costa testified that because there is no known cause for PNLH, he came up with a hypothesis for a cause—specifically that because arsenic can cause increased lymphocyte proliferation, it can also cause PNLH. [Docket No. 245-3, at 13-14]. However he admitted there is no evidence in the literature to support that hypothesis. *Id.*

Similarly, Dr. Lantz testified that his opinion is that arsenic induces immunosuppression, which leads to the inability of the lung to deal with infection or other foreign agents, which leads to inflammation and can manifest as PNLH. [Docket No. 245-2, at 38-39]. Dr. Lantz admitted, however, that no one has written an opinion that arsenic can depress the immune system such that it facilitates or aids in the development of PNLH. *Id.* at 40, 46. In fact, he stated that he used the word “possible,” meaning it could have occurred, instead of “probable,” meaning an increased likelihood that it occurred, in rendering his opinion on the possible role arsenic can play in the development of NLH because “there is no association between arsenic and causation of the disease.” *Id.* at 48. Further, Dr. Lantz stated he was the only person he knew who has ever rendered an opinion that arsenic can depress the immune system such that it facilitates or aids in

the development of PNLH and before submitting his work for peer review, he would want some data to back it up, stating “we don’t have any data whatsoever.” *Id.* at 40. Plaintiffs offer no reasoning in their Objections as to how Magistrate Judge Smith erred in her analysis of the literature or that Drs. Lantz’s and Costa’s opinions require speculation. Nor do they address the fact that the experts agree no one knows what causes PNLH to develop and they are unable to cite to any literature that supports an association between arsenic and PNLH.

Further, to the extent Plaintiffs argue that both experts identify a credible physiological process by which arsenic can cause NLH, presumably by causing an immune deficiency and/or through the proliferation of lymphocytes, this argument fails for the same reasons—it is not supported by any evidence or medical literature that because arsenic can cause an immune deficiency or increase proliferation of lymphocytes, it can also cause PNLH. Both experts admit there is no literature supporting an association between arsenic and PNLH. Indeed, Dr. Costa testified that while he cites 14 articles for the proposition that arsenic can affect lymphocyte proliferation, none of these articles state that arsenic is associated with PNLH. [Docket No. 245-3, at 13]. Similarly, Dr. Lantz conceded that while the studies he cites suggest chronic exposure to arsenic has the potential to impair immune responses that can lead to increased risk of disease, the reports do not conclude that arsenic causes or contributes to NLH in the lung. [Docket No. 245-2, at 16, 34-35, 37, 40, 46]. Again, the Report and Recommendation meticulously outlines the doctors’ opinions as well as the lack of support in the literature cited by the experts. Plaintiffs do not offer a specific challenge to the analysis or attempt to explain how the opinions meet *Daubert* principles. Instead, the record supports a finding that both Drs. Lantz and Costa substituted their own *ipse dixit* for scientific proof on the essential point that because arsenic can

cause increased proliferation of lymphocytes or cause an immune deficiency, it can also cause PNLH. There is simply no support for these opinions. Thus, there is too great an analytical gap between the data and the opinion proffered.

The Court is mindful that objections to a Report and Recommendation are limited in scope, alleging error in the facts or law relied upon by the Magistrate Judge. “[A]n ‘objection’ that does nothing more than state a disagreement with a magistrate’s suggested resolution, or simply summarizes what has been presented before, is not an ‘objection’ as that term is used in this context.” See *VanDiver v. Martin*, 304 F. Supp. 2d 934, 938 (E.D. Mich. 2004); *Holl v. Potter*, No. C-1-09-618, 2011 WL 4337038, at *1 (S.D. Ohio. Sept. 15, 2011) (holding that “objections that merely restate arguments raised in the memoranda considered by the Magistrate Judge are not proper, and the Court may consider such repetitive arguments waived”). Such an “objection” fails to put the district court on notice of any potential errors in the Magistrate Judge’s Report and Recommendation. *VanDiver*, 304 F. Supp. 2d at 938. Nor may a party present new evidence add additional claims or present new evidence. See *Kloss v. RBS Citizens, N.A.*, 996 F.Supp.2d 574, 582 (E.D. Mich. 2014) citing *Murr v. United States*, 200 F.3d 895, 902 n.1 (6th Cir. 2000).

The Report and Recommendation meticulously examines the testimony of Drs. Saggari, Lantz, Costa and Stark and the references on which they claimed to have relied. Judge Smith determined that the available medical and scientific literature does not support an association between PNLH and CCA, and that the Plaintiffs’ experts’ opinions were too speculative to be admissible. The Court having reviewed the objections, as well as the record, finds nothing therein which would contradict or call into question the findings of the Magistrate. Thus, the

Court shall adopt the report and recommendation as and for its own opinion.

Accordingly, **IT IS HEREBY ORDERED** that the Magistrate Judge's report and recommendation [Docket No. 295] is hereby, **APPROVED** and **ADOPTED** as for the opinion of the Court.

IT IS FURTHER ORDERED:

1. Defendants' Joint Motion to Exclude Testimony Regarding the Alleged Cause of Pulmonary Nodular Lymphoid Hyperplasia pursuant to Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.* [Docket No. 245] be **SUSTAINED**;
2. Plaintiffs' Motions to Exclude or Limit the Opinions and Testimony of Defendants' Experts Michael Koss, M.D. and Philip S. Guzelian, M.D. [Docket Nos. 254 and 255) be **OVERRULED AS MOOT**; and
3. Defendants' Joint Motion for Summary Judgment Based on Plaintiffs' Failure to Prove General or Specific Causation [Docket No. 252] be **SUSTAINED** as it pertains to to Mr. McCarty's PNLH and **OVERRULED** as it pertains to his non-PNLH health problems.

This 3/31 day of March, 2016.



Signed By:

Henry R. Wilholt, Jr.

United States District Judge