

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

NATALIE KONRICK

CIVIL ACTION

VERSUS

NO: 14-524

EXXON MOBIL CORPORATION, AND
CHALMETTE REFINING, LLC

SECTION: R

ORDER AND REASONS

Defendants Exxon Mobil Corporation and Chalmette Refining, LLC move to exclude the testimony of plaintiff's three general causation experts, Drs. Robert Harrison, Cynthia Bearer, and Laurel Waters. Having reviewed the parties' briefs, along with each expert's report and the studies cited therein, the Court grants defendants' motion because it finds that each doctor's general causation opinion is based on an unreliable methodology.

I. BACKGROUND

Plaintiff Natalie Konrick filed this personal injury and wrongful death action against defendants. Plaintiff alleges that, while pregnant, she worked as a security guard at the Exxon Chalmette Refinery, where her tasks included checking crew members' identification badges and bags as they entered the

facility.¹ According to plaintiff, this work exposed her and her fetus to toxic substances, which caused her to suffer fetal demise and a stillbirth delivery.² Plaintiff further alleges that defendants negligently designed and maintained the refinery and that they negligently failed to warn refinery personnel of the reproductive hazards associated with exposure.³ She seeks damages for the physical and emotional trauma associated with her stillbirth, as well as for the wrongful death of her stillborn fetus.⁴

Plaintiff's total employment at the refinery lasted from January to April 2013. On April 9, 2013, plaintiff was admitted to the hospital after experiencing pelvic pressure, decreased fetal movement, and vaginal leakage.⁵ The next day, plaintiff's doctor induced labor, and plaintiff "delivered her stillborn daughter."⁶ An autopsy revealed that the child was 27 weeks of gestational age and that it exhibited various anatomical anomalies, including microcephaly (a term which, according to plaintiff's expert pathologist, means

¹ R. Doc. 1 at 2-3.

² *Id.* at 7, 9, 10.

³ *Id.* at 7-9.

⁴ *Id.* at 9-10.

⁵ *Id.* at 5.

⁶ *Id.*

"severely low head circumference"),⁷ a cleft palate, and nonunion of the mandibular symphysis.⁸ The autopsy report identified the likely cause of fetal demise as "decreased uteroplacental blood flow with subsequent obliterative fetal vasculopathy and fetal hypoxemia."⁹ The report noted that plaintiff reported having been exposed to benzene during pregnancy, but that while "benzene has been shown to cross the human placenta[,] . . . [the] effects of benzene exposure in pregnant women [are] not well understood."¹⁰

Plaintiff alleges that her stillbirth resulted from general and acute exposure to toxic substances at the refinery. Plaintiff's complaint alleges exposure to two substances in particular: benzene and hydrogen sulfide.¹¹ Specifically, plaintiff alleges that because her guard post was located near the refinery's dock, "she was exposed to benzene from the loading and unloading of ships and barges on a daily basis."¹² In addition, plaintiff alleges that a pipeline leak on the morning of April 3 exposed her to elevated levels of

⁷ R. Doc. 32-8 at 8.

⁸ R. Doc. 32-11 at 3.

⁹ *Id.* at 6.

¹⁰ *Id.*

¹¹ R. Doc. 1 at 2-3.

¹² *Id.*

benzene and hydrogen sulfide over the course of several days.¹³ Plaintiff's exposure expert, Dr. David Mitchell, a forensic meteorologist, expands the list of chemicals at issue. Using an air dispersion model, Dr. Mitchell estimates the maximum concentrations of various substances in the air as a result of emissions within the refinery.¹⁴ Based on this analysis, he opines that plaintiff was exposed to "significant" or "non-zero" levels of benzene and hydrogen sulfide, as well as toluene, ethyl-benzene, xylene, and other chemical compounds.¹⁵ Dr. Mitchell does not, however, quantify plaintiff's level of exposure to any particular substance.

To demonstrate that occupational exposure caused her stillbirth, plaintiff offers the testimony of three medical experts: Drs. Harrison, Bearer, and Waters. In their expert reports, each expert opines that the exposures alleged by plaintiff and described by Dr. Mitchell can cause adverse reproductive outcomes of the type identified in plaintiff's complaint. Defendants now move to exclude each expert's opinion, arguing that each is based on an unreliable methodology.¹⁶

¹³ *Id.* at 3.

¹⁴ R. Doc. 34-6 at 3.

¹⁵ *Id.* at 27.

¹⁶ R. Doc. 32-2. In a separate motion, defendants also challenge the reliability of plaintiff's exposure expert, Dr. Mitchell. *See* R. Doc. 34.

II. LEGAL STANDARD

In this toxic torts case, plaintiff alleges that general and acute exposure to benzene, hydrogen sulfide, and other substances caused her stillbirth at 27 weeks of gestation. Accordingly, plaintiff must show general causation--that these substances can cause stillbirths--and specific causation--that exposure to defendants' substances caused plaintiff's stillbirth. *See Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007) ("General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury."). A court may admit specific-causation evidence only after the plaintiff has produced admissible evidence on general causation. *See id.* ("[I]f it concludes that there is admissible general-causation evidence, the district court must determine whether there is admissible specific-causation evidence.").

A district court has considerable discretion to admit or exclude expert testimony under Rule 702. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 138–39 (1997); *Seatrax, Inc. v. Sonbeck Int'l, Inc.*, 200 F.3d 358, 371 (5th Cir. 2000). Rule 702, which governs the admissibility of expert witness testimony, provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (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.

Fed.R.Evid. 702.

In *Daubert v. Merrell Dow Pharms., Inc.*, the Supreme Court held that Rule 702 requires the district court to act as a gatekeeper to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. 579, 589 (1993); *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999) (clarifying that the *Daubert* gatekeeping function applies to all forms of expert testimony). The Court's gatekeeping function thus involves a two-part inquiry into reliability and relevance.

First, the Court must determine whether the proffered expert testimony is reliable. The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence. *See Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998). The reliability inquiry requires the Court to assess whether the reasoning or methodology underlying the expert's testimony is valid. *See Daubert*, 509 U.S. at 592–93. The aim is to exclude expert testimony based merely on subjective belief or unsupported

speculation. *See id.* at 590. The Court in *Daubert* articulated a flexible, non-exhaustive, five-factor test to assess the reliability of an expert's methodology: (1) whether the expert's theory can be or has been tested; (2) whether the theory has been subject to peer review and publication; (3) the known or potential rate of error of a technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) the degree to which the technique or theory has been generally accepted in the scientific community. *Id.* at 593–95. The Supreme Court has emphasized, however, that these factors "do not constitute a 'definitive checklist or test.'" *Kumho*, 526 U.S. at 150 (quoting *Daubert*, 509 U.S. at 593). Rather, district courts "must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Id.* at 152. Courts have also considered whether experts are "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995). They have examined whether the expert has adequately accounted for obvious alternative explanations. *See Claar v. Burlington N.R.R.*, 29 F.3d 499, 502 (9th Cir. 1994). They have also asked whether the expert "is being as careful as he would be in his regular

professional work outside his paid litigation consulting." *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997).

A district court's gatekeeper function does not replace the traditional adversary system or the role of the jury within this system. *See Daubert*, 509 U.S. at 596. As the Supreme Court noted in *Daubert*: "Vigorous 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." *Id.* The Fifth Circuit has held that, in determining the admissibility of expert testimony, district courts must accord proper deference to "the jury's role as the proper arbiter of disputes between conflicting opinions" and that, generally, "questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility." *United States v. 14.38 Acres of Land, More or Less Situated in Leflore Cnty., Miss.*, 80 F.3d 1074, 1077 (5th Cir. 1996) (quoting *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987)) (internal quotation marks omitted). Nonetheless, expert testimony "must be reliable at each and every step or else it is inadmissible," and "[t]he reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion, *et alia.*" *Knight*, 482 F.3d at 355 (internal quotation marks

omitted). If the "expert's opinion is based on insufficient information, the analysis is unreliable." *Paz v. Brush Engineered Materials, Inc.*, 555 F.3d 383, 388 (5th Cir. 2009).

In *Joiner*, the Supreme Court explained that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." 522 U.S. at 146. Rather, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id.*; *see also LeBlanc v. Chevron USA, Inc.*, 396 F. App'x 94, 98 (5th Cir. 2010).

The Court next considers whether the expert's reasoning or methodology is relevant. The question here is whether the reasoning or methodology "fits" the facts of the case and will thereby assist the trier of fact to understand the evidence. *See Daubert*, 509 U.S. at 591.

In fulfilling its role as a gatekeeper, the Court recognizes that "the courtroom is not the place for scientific guesswork, even of the inspired sort." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996). Rather, "[l]aw lags science; it does not lead it." *Id.* The Court is mindful of the following Supreme Court guidance:

[T]here are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other

hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment--often of great consequence--about a particular set of events in the past. We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.

Daubert, 509 U.S. at 596–97.

III. DISCUSSION

A. Introduction

Defendants contend that there is no scientific basis for concluding that exposure to benzene, hydrogen sulfide, or the other chemicals identified by plaintiff's exposure expert, Dr. Mitchell, can cause stillbirths at 27 weeks of gestation. To prove that these substances can cause stillbirths in the general population, plaintiff offers the testimony of three experts: Drs. Harrison, Bearer, and Waters.

Under *Daubert*, the Court's focus is on methodology. According to their reports, each expert relies heavily upon epidemiological studies concerning exposure to various toxins and adverse reproductive effects. Epidemiology provides the best evidence of general causation in toxic tort cases. *See Brock*

v. Merrell Dow Pharms., Inc., 874 F.2d 307, 311 (5th Cir. 1989), *modified by* 884 F.3d 166 (5th Cir. 1989); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) (stating "that epidemiology is the best evidence of general causation in a toxic tort case"). This is not to say that epidemiologic evidence "is a necessary element in all toxic tort cases," but "it is certainly a very important element." *Brock*, 874 F.2d at 313.

Epidemiology is the study of "the incidence, distribution, and etiology of disease in human populations." Federal Judicial Center, Reference Manual on Scientific Evidence 551 (3d ed. 2011). As the Fifth Circuit has explained:

Epidemiology attempts to define a relationship between a disease and a fact suspected of causing it.... To define that relationship, the epidemiologist examines the general population, comparing the incidence of the disease among those people exposed to the factor in question to those not exposed. The epidemiologist then uses statistical methods and reasoning to allow her to draw a biological inference between the factor being studied and the disease's etiology.

Brock, 874 F.2d at 311.

To determine whether a causal relationship exists between an agent and a disease, an epidemiologist must first identify an association. An association occurs when "two events (*e.g.*, exposure to a chemical agent and development of disease) . . . occur more frequently together than one would expect by chance." Reference Manual at 552 n. 7. An association, by itself, is not

equivalent to causation. *Id.* at 552. Unlike an association, "[c]ausation is used to describe the association between two events when one event is a necessary link in a chain of events that results in the effect." *Id.* at 552 n. 7. The Reference Manual indicates that "[a]ssessing whether an association is causal requires an understanding of the strengths and weaknesses of a study's design and implementation, as well as a judgment about how the study's findings fit with other scientific knowledge." *Id.* at 553. Because "all studies have 'flaws' in the sense of limitations that add uncertainty about the proper interpretation of results," the key questions in evaluating epidemiologic evidence "are the extent to which a study's limitations compromise its findings and permit inferences about causation." *Id.* at 553.

Once an association is found, "researchers consider whether the association reflects a true cause-effect relationship;" that is, whether "an increase in the incidence of disease among the exposed subjects would not have occurred had they not been exposed to the agent." *Id.* at 597–98. Alternative explanations, "such as bias or confounding factors," should first be considered. *Id.* at 598. If alternative explanations are not present, researchers apply the "Bradford Hill criteria" to evaluate whether an agent could be a cause of a disease. *See In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1233 (D. Colo. 1998). The Bradford Hill criteria are: (1) temporal relationship; (2)

strength of the association; (3) dose-response relationship; (4) replication of findings; (5) biological plausibility; (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge. Reference Manual at 600. The

Reference Manual cautions:

There is no formula or algorithm that can be used to assess whether a causal inference is appropriate based on these guidelines. One or more factors may be absent even when a true causal relationship exists. Similarly, the existence of some factors does not ensure that a causal relationship exists. Drawing causal inferences after finding an association and considering these factors requires judgment and searching analysis, based on biology, of why a factor or factors may be absent despite a causal relationship, and vice versa. Although the drawing of causal inferences is informed by scientific expertise, it is not a determination that is made by using an objective or algorithmic methodology.

Id.

Under *Daubert*, "courts must carefully analyze the studies on which experts rely for their opinions before admitting their testimony." *Knight*, 482 F.3d at 355; *see also Brock*, 874 F.2d at 309–10 ("[C]ourts must critically evaluate the reasoning process by which experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them."); *Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 799 (E.D. La. 2011) ("Whether epidemiological studies support an expert's

opinion on the question of general causation in a toxic tort case is critical to determining the reliability of the opinion."). Courts "may exclude expert testimony based on epidemiological studies where the studies are insufficient, whether considered individually or collectively, to support the expert's causation opinion." *Baker v. Chevron USA, Inc.*, 680 F. Supp.2d 865, 875 (S.D. Ohio 2010) (citing *Joiner*, 522 U.S. at 156–57). A court cannot exclude expert testimony simply because it disagrees with the expert's conclusions, but an expert's conclusions must be connected to existing data by more than the mere say-so of the expert.

[C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion offered.

Joiner, 522 U.S. at 146.

Courts have excluded expert opinions on causation based on epidemiologic and other scientific studies for a number of reasons. First, studies that "do not represent statistically significant results" may not provide a reliable foundation for a general causation opinion in a toxic torts case. *LeBlanc*, 396 F. App'x at 99 (citing *Joiner*, 522 U.S. at 145 (holding that a study showing a statistically insignificant increase in disease incidence

following exposure to the allegedly causal chemical can be rejected by the district court as a foundation for the expert's opinion)). The results of epidemiological studies are often expressed in terms of a relative risk (RR)¹⁷ or an odds ratio (OR).¹⁸ An RR or OR of 1.0 indicates that the number of observed incidences of a disease or condition equals that of expected cases. In contrast, a figure higher than 1.0 indicates that the number of observed incidences exceeds that of expected cases; in other words, it indicates a positive association. A study is considered statistically significant only when the results--*e.g.*, RR or OR--are expressed with a 95% confidence interval, and when that interval does not include the number 1.0. *See Brock*, 874 F.2d at 312. As the Fifth Circuit has explained:

[I]f a study concluded that the relative risk for [a toxin] was 1.30, which is consistent with a 30% elevated risk of harm, but the confidence interval was from 0.95 to 1.82, then no statistically significant conclusions could be drawn from this study because the relative risk, when adjusted by the confidence interval, includes

¹⁷ "The relative risk is a number which describes the increased or decreased incidence of the disease in question in the population exposed to the factor as compared to the control population not exposed to the factor. . . . A relative risk of 1.0 means that the incidence of [the disease or condition] in the two groups were the same. A relative risk greater than 1.0 means that there [was more of the disease or condition in the group exposed to the factor]." *Brock*, 874 F.2d at 312.

¹⁸ "A measure of association, often used in epidemiology. For example, if 10% of all people exposed to a chemical develop a disease, compared with 5% of people who are not exposed, then the odds of the disease in the exposed group are $10/90 = 1/9$, compared with $5/95 = 1/19$ in the unexposed group. The odds ratio is $(1/9)/(1/19) = 19/9 = 2.1$. An odds ratio of 1 indicates no association." Reference Manual at 291.

1.0. Again, it is important to remember that the confidence interval attempts to express mathematically the magnitude of possible error, due to the above mentioned sources as well as others, and therefore a study with a relative risk of greater than 1.0 must always be considered in light of its confidence interval before one can draw conclusions from it.

Id.

Second, a study that provides merely "a suggestion or possibility of a relationship is insufficient for a causation opinion." *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1233; *see also Knight*, 482 F.3d at 353 ("Although the study's 'suggestion' could theoretically provide some basis for the conclusion that diesel exhaust causes bladder cancer, it does not, as appellants argue, 'clearly support' that conclusion."). The same is true of a study that "only provides an arguable inferential starting point" for finding a causal relationship. *LeBlanc*, 396 F. App'x at 99. Studies that are inconclusive and merely recommend that further studies be done are likely to fall into this category. *See In re Breast Implant Litig.*, 11 F. Supp. 2d at 1231. This is not to suggest that studies must unequivocally support a general causation opinion, but they must provide more than a hypothesis.

Third, a study that notes "that the subjects were exposed to a range of substances and then nonspecifically note[s] increases in disease incidence" can be disregarded. *LeBlanc*, 396 F. App'x at 99; *see also Joiner*, 522 U.S. at 146

(holding that an expert's reliance on a study was misplaced when the subjects of the study "had been exposed to numerous potential carcinogens"); *Knight*, 482 F.3d at 353 ("Of all the organic solvents the study controlled for, it could not determine which led to an increased risk of cancer. . . . The study does not provide a reliable basis for the opinion that the types of chemicals appellants were exposed to could cause their particular injuries in the general population."). Likewise, studies that do not examine the precise disease or condition at issue may not provide good grounds for an expert's opinion. *See Henricksen v. Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1171–75 (E.D. Wa. 2009) (calling into question the relevance of studies that did not study the specific disease at issue).

Fourth, when a study's authors expressly disclaim the causal relationship that the expert relies upon the study to prove, the study likely does not provide a reliable basis for the expert's opinion. *See Joiner*, 522 U.S. at 145 (holding that a study did not support an expert's opinion on causation when the study was "unwilling to say that PCB exposure had caused cancer"); *LeBlanc*, 396 F. App'x at 100 ("The district court properly rejected the studies as supporting causation because the authors of the studies concluded that there was no proof of causation."); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1248 (11th Cir.

2005) (criticizing an expert for drawing "unauthorized conclusions from limited data--conclusions the authors of the study do not make").

B. Dr. Harrison

Plaintiff's first general causation expert, Dr. Harrison, is a medical doctor board certified in occupational and internal medicine. As to general causation, Dr. Harrison states: "occupational exposure to organic solvents is a cause of adverse reproductive outcomes, including decreased uterine blood flow with fetal hypoxemia leading to fetal demise."¹⁹ The reported basis for Dr. Harrison's conclusion is his review of published epidemiological reports and other relevant data, including "human case reports, animal data, experimental studies, laboratory data, mechanistic data, and other types of data as well, including unpublished studies."²⁰ Specifically, Dr. Harrison cites 29 epidemiological studies, which he summarizes according to the observed outcome and the reported results.²¹ In addition, Dr. Harrison states that he "followed generally accepted methodology for determining general causation," including application of the Bradford Hill criteria.²²

Having reviewed the parties' briefings and submissions, Dr. Harrison's report and deposition testimony, and the relevant scientific literature, the

¹⁹ R. Doc. 32-7 at 17. ("Dr. Harrison Report").

²⁰ *Id.* at 3.

²¹ *Id.* at 20-22.

²² *Id.* at 3-4.

Court finds that Dr. Harrison's general causation opinion is not grounded in a reliable methodology. Dr. Harrison's methodology is flawed because he relies on multiple studies that do not reliably support his conclusion. First, Dr. Harrison relies on a number of studies that do not isolate exposure to the substances at issue, or do not provide exposure metrics. Second, many of the studies upon which Dr. Harrison relies examine the incidence of spontaneous abortion or miscarriage, rather than stillbirth, the outcome at issue in this case. Third, Dr. Harrison relies on studies that do not exhibit statistically significant results. Finally, in several instances, Dr. Harrison cherry-picked data from studies that do not otherwise support his conclusion, reached conclusions that the authors of the study did not make, and failed to explain contrary results. Compounding these shortcomings is that, despite citing studies that are inconsistent in both their subject matter and their results, Dr. Harrison does not present a meaningful analysis in which he reconciles the contradicting results and explains their relevance to the facts of this case.

1. Dr. Harrison's Reliance on Studies that Do Not Isolate Exposure to the Substances at Issue or Do Not Provide Exposure Metrics

A basic flaw in Dr. Harrison's methodology is that he relies heavily on studies that focus on "solvents" or "organic solvents" as a class, instead of the

specific substances that allegedly caused plaintiff's stillbirth.²³ *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) ("Even minor deviations in molecular structure can radically change a particular substance's properties and propensities." (citing *Schudel v. Gen. Elec. Co.*, 120 F.3d 991, 996-97 (9th Cir. 1997))); Wennborg, H., *et al.*, *Adverse Reproduction Outcomes Among Employees Working in Biomedical Research Laboratories*, 28 SCAND. J. ENV'T HEALTH 5 (2002) (noting "different types of solvents [may] have different effects on reproduction"); Khattak, S., *et al.*, *Pregnancy Outcome Following Gestational Exposure to Organic Solvents*, 281 J. AM. MEDICAL ASS'N 1106 (1999) ("[O]rganic solvents, although traditionally clustered together, are a diverse group of compounds that should not be expected to cause similar patterns of reproductive toxic effects."). Because these studies do not isolate exposure to benzene, hydrogen sulfide, or the chemicals identified by Dr. Mitchell from exposure to other substances, they cannot reliably support Dr. Harrison's opinion that the exposure alleged by plaintiff can cause stillbirths in the general population. *See Leblanc*, 396

²³ The parties do not dispute that the term "organic solvents" refers to a broad range of substances that includes benzene, toluene, heptane, and hexane, among others. R. Doc. 44 at 12; R. Doc. 53 at 5. Plaintiff apparently concedes, however, that hydrogen sulfide is not an organic solvent. *See* R. Doc. 44 at 12 (noting that "organic solvents are carbon-based solvents capable of dissolving or dispersing one or more substances and concluding that "benzene, toluene, heptane, and hexane are all organic solvents").

F. App'x at 99 (noting a study indicating "that the subjects were exposed to a range of substances and then nonspecifically note increases in disease incidence" can be disregarded); *Knight*, 482 F.3d at 353 (finding study that focused on organic solvents as a class without determining which solvent led to an increased risk of cancer did not provide reliable basis for opinion that benzene could cause plaintiffs' specific injuries); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 270 (2d Cir. 2002) (excluding general causation expert who relied upon articles that "involved individuals who were exposed to a variety of solvents, many of which were not contained in the paint [plaintiff] used").

For instance, Dr. Harrison's expert report cites, without any explanation or elaboration, Attarchi, M., *et al.*, *Assessment of Time to Pregnancy and Spontaneous Abortion Status Following Occupational Exposure to Organic Solvents*, 85 INT'L ARCHIVES OCCUPATIONAL ENVTL HEALTH 295 (2012),²⁴ in support of his general causation opinion. Dr. Harrison's report fails to note that the workers in the study were exposed to a number of different organic solvents, including formaldehyde, phenol, hexane, and chloroform--substances to which, as Dr. Harrison admitted in his deposition,²⁵

²⁴ Dr. Harrison Report at 20.

²⁵ R. Doc. 53-1 at 5.

plaintiff was never exposed. Nor does the report acknowledge the study's guidance that because workers "may have exposure to a mixture of organic solvents, it is difficult to attribute spontaneous abortion to any specific solvent." Similarly, Dr. Harrison's report cites Agnesi, R., *et al.*, *Risk of Spontaneous Abortion and Maternal Exposure to Organic Solvents in the Shoe Industry*, 69 INT'L ARCHIVES OCCUPATIONAL ENVTL HEALTH 311 (1997),²⁶ without noting that the workers involved were exposed primarily to ethylacetate, methylethylketone, hexane isomers, and cyclohexane. Though Dr. Harrison acknowledged that none of these substances is at issue,²⁷ his report fails to explain why this study is relevant to plaintiff's case. Dr. Harrison's reliance on a number of other studies is similarly flawed. *See* Garlantezec, R., *et al.*, *Maternal Occupational Exposure to Solvents and Congenital Malformations*, 66 OCCUPATIONAL ENVL MEDICINE 456 (2009) (examining risks associated with maternal exposure to solvents as a group, without specifying which "specific chemical classes of solvents" were responsible for observed increase in incidence of congenital malformation);²⁸ Holmberg, P., *et al.*, *Oral Clefts and Organic Solvent Exposure During*

²⁶ Dr. Harrison Report at 20.

²⁷ R. Doc. 53-1 at 9.

²⁸ Dr. Harrison Report at 20.

Pregnancy, 50 INTL ARCHIVES OCCUPATIONAL ENVTL HEALTH 371 (1982) (noting employees were exposed to a range of solvents, including lacquer petrol, xylene, and methylethylketone);²⁹ Huel, G., *et al.*, *Evidence for Adverse Reproductive Outcomes Among Women Microelectronic Assembly Workers*, 47 BRITISH J. INDUS. MEDICINE 400 (1990) (noting employees were potentially exposed to, among other solvents, chlorofluorocarbons, chlorinated hydrocarbons, glycol ethers, and alcohol).³⁰

Dr. Harrison also cited a number of studies that specifically examined substances such as glycol ethers and others that are absent from plaintiff's complaint and Dr. Mitchell's exposure analysis. *See e.g.*, Brender, J., *et al.*, *Maternal Residential Proximity to Chlorinated Solvent Emissions and Birth Defects in Offspring*, 13 ENVTL HEALTH 96 (2014) (examining risks associated with exposure to carbon tetrachloride, ethyl chloride, trichloroethane, and other chlorinated solvents);³¹ Cordier, S., *et al.*, *Congenital Malformation and Maternal Occupational Exposure to Glycol Ethers*, 8 EPIDEMIOLOGY 355 (1997) (evaluating risk of congenital

²⁹ *Id.* at 21.

³⁰ *Id.*

³¹ *Id.* at 20.

malformations related to glycol ether exposure);³² Kyyronen, P., *et al.*, *Spontaneous Abortions and Congenital Malformations Among Women Exposed to Tetrachloroethylene in Dry Cleaning*, 43 J. EPIDEMIOLOGY COMMUNITY HEALTH 346 (1989) (finding exposure to tetrachloroethylene significantly associated with spontaneous abortions).³³ Dr. Harrison has made no attempt to explain why these studies can reliably support the conclusion that the exposure to benzene, hydrogen sulfide, or any of the other chemicals at issue can cause stillbirths or congenital anomalies. Without demonstrating how this literature applies to the specific exposures alleged by plaintiff, Dr. Harrison's reliance on these studies leaves "too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146.

Dr. Harrison's reliance on studies that do not quantify exposure levels is equally problematic. For instance, many of the studies on which Dr. Harrison relies examined women in certain occupational groups, rather than directly examining exposure to benzene, hydrogen sulfide, or any other chemical at issue. *See* Axelsson, G., *et al.*, *Exposure to Solvents and Outcome of Pregnancy in University Laboratory Employees*, 41 BRITISH J. INDUS. MEDICINE 305 (1984) (examining outcome of pregnancy among personnel

³² *Id.*

³³ *Id.* at 21.

employed in university laboratory and noting "laboratory work is a general term that implies exposure to a variety of agents");³⁴ Axelsson, G. and Molin, I., *Outcome of Pregnancy Among Women Living Near Petrochemical Industries in Sweden*, 17 INTL J. EPIDEMIOLOGY 363 (1988) (finding increase in miscarriages among women who worked for petrochemical companies, without any elaboration as to the chemicals to which the workers were exposed other than note that "a large number of chemicals, including ethylene oxide, are used at these plants");³⁵ Heidam, L., *Spontaneous Abortions Among Dental Assistants, Factory Workers, Painters, and Gardening Workers: A Follow Up Study*, 38 J. EPIDEMIOLOGY COMMUNITYHEALTH, 149 (1984) (examining risk of spontaneous abortion among women in various professions, but acknowledging that "information on chemical exposure is not precise, and intensity and time of exposure in the pregnancy is unknown").³⁶ While some of these occupations may be an imprecise proxy for exposure to the substances at issue here, these studies do not indicate what substances and at what levels the workers were actually exposed. Moreover, given the wide range of occupations at issue--the studies

³⁴ *Id.* at 20.

³⁵ *Id.*

³⁶ *Id.*

focus on dental hygienists, painters, gardeners, laboratory technicians, factory workers, and others--it is likely that workers were exposed to a wide range of substances, any one of which could potentially account for the observed outcomes. *See* ATSDR, Toxicological Profile for Benzene, 225 (2007) (highlighting "problems in controlling for concomitant exposures to other chemicals" as a factor limiting studies on the reproductive effects of occupational benzene exposure).

2. *Studies that Focus on Spontaneous Abortion or Miscarriage, Instead of Later-Stage Pregnancy Loss*

Second, many of the studies upon which Dr. Harrison relies examined the risk of spontaneous abortions or miscarriage--terms which, according to plaintiff's expert neonatologist, refer to a loss of pregnancy before the twentieth week of gestation.³⁷ By contrast, plaintiff's pregnancy loss occurred at 27 weeks of gestation. Medical experts generally refer to such late-stage pregnancy loss as stillbirth.³⁸ In his deposition, Dr. Harrison acknowledged the distinction between these outcomes:

Q. The Xu, X-u, paper dealt with spontaneous abortion, correct?

A. Correct.

³⁷ R. Doc. 32-9 at 4.

³⁸ *Id.*

Q. And if--and can we agree that Miss Konrick [did] not suffer spontaneous abortion, correct?

A. Correct.³⁹

Nonetheless, Dr. Harrison's report cites, without any explanation, numerous studies that examine the association between solvent exposure and miscarriage or spontaneous abortion. *See e.g.*, Agnesi, R., *et al.*, *Risk of Spontaneous Abortion and Maternal Exposure to Organic Solvents in the Shoe Industry*, 69 INT'L ARCHIVES OCCUPATIONAL ENVTL HEALTH 311 (1997);⁴⁰ Axelsson, G., *et al.*, *Exposure to Solvents and Outcome of Pregnancy in University Laboratory Employees*, 41 BRITISH J. INDUS. MEDICINE 305 (1984);⁴¹ Lindholm, M.L., *et al.*, *Effects of Parental Occupational Exposure to Solvents and Lead on Spontaneous Abortion*, 18 SCAND. J. WORK, ENVT, HEALTH 37 (1992);⁴² Ng, T., *et al.*, *Risk of Spontaneous Abortion in Workers Exposed to Toluene*, 49 BRITISH J. INDUS. MEDICINE 804 (1992);⁴³ Xu, X., *et al.*, *Association of Petrochemical Exposure with Spontaneous Abortion*, 55

³⁹ R. Doc. 53-1 at 6.

⁴⁰ Dr. Harrison Report at 20.

⁴¹ *Id.*

⁴² *Id.* at 21

⁴³ *Id.*

OCCUPATIONAL ENVIRONMENTAL MEDICINE 31(1998).⁴⁴ Dr. Harrison's expert report does not elaborate on these citations. Nor does it explain why these studies are relevant, even though the workers involved were exposed to solvents earlier in their pregnancies than plaintiff alleges, and they experienced an injury that Dr. Harrison acknowledges to be different from plaintiff's own. Dr. Harrison's failure to explain his reliance on these studies diminishes his reliability. *See Knight*, 482 F.3d at 355 ("[T]he expert's testimony must be reliable at each and every step or else it is inadmissible.").

3. *Studies that Do Not Exhibit Statistically Significant Results*

Another weakness in Dr. Harrison's methodology is his reliance on studies exhibiting results that do not reach statistical significance. As the Fifth Circuit holds, studies "showing a statistically insignificant increase in disease incidence following exposure to the alleged causal chemical can properly be rejected by the district court as a foundation for the expert's opinion." *Leblanc*, 396 F. App'x at 99 (citing *Joiner*, 522 U.S. at 145). Some of the studies upon which Dr. Harrison relies did not produce statistically significant results, and his reliance on them is therefore questionable.⁴⁵ *See Axelsson, G.*,

⁴⁴ *Id.* at 22.

⁴⁵ Though plaintiff characterizes some of these studies as statistically significant, she does not elaborate or provide any argument to support her position. As the Fifth Circuit holds, "if the confidence interval [of an epidemiological study] is so great that it

et al., *Exposure to Solvents and Outcome of Pregnancy in University Laboratory Employees*, 41 BRITISH J. INDUS. MEDICINE 305 (1984);⁴⁶ Heidam, L., *Spontaneous Abortions Among Dental Assistants, Factory Workers, Painters, and Gardening Workers: A Follow Up Study*, 38 J. EPIDEMIOLOGY COMMUNITY HEALTH, 149 (1984);⁴⁷ Hemminki, O., *et al.*, *Low Birthweight, Congenital Malformations, and Spontaneous Abortions Among Dry-Cleaning Workers in Scandinavia*, 16 SCAND. J. WORK, ENV'T, HEALTH, 163 (1990);⁴⁸ Kyyronen, P., *et al.*, *Spontaneous Abortions and Congenital Malformations Among Women Exposed to Tetrachloroethylene in Dry Cleaning*, 43 J. EPIDEMIOLOGY COMMUNITY HEALTH 346 (1989);⁴⁹ Wennborg, *Adverse Reproductive Outcomes Among Employees Working in Biomedical Research Laboratories*, 28 SCAND. J. WORK, ENV'T, HEALTH 5 (2002).⁵⁰

includes the number 1.0, then the study will be said to show no statistically significant association between the factor and the disease." *Brock*, 874 F.2d at 312. In each of these studies, the 95% confidence interval includes 1.0. Contrary to plaintiff's contention, such studies are not statistically significant.

⁴⁶ Dr. Harrison Report at 20.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.* at 21.

⁵⁰ *Id.*

4. *Dr. Harrison Cherry-Picked Data, Reached Conclusions that the Authors of the Studies Did Not Make, and Failed to Explain Contrary Results*

In several instances, Dr. Harrison cites studies selectively, highlighting only data that supports his position in a way that undermines the reliability of his methodology. For example, Dr. Harrison's expert report cites Laumon, B., *et al.*, *Exposure to Organic Solvents During Pregnancy and Oral Clefts: A Case Control Study*, 10 REPROD. TOXICOLOGY 15 (1996),⁵¹ for its observation of an association between oral clefts (such as the cleft palate observed in plaintiff's fetus) and maternal exposure to any organic solvent. The same study, however, separately examined the risks associated with exposure to aromatic solvents--a sub-category of solvents that includes benzene--and did not observe a statistically significant association. That Dr. Harrison disregards this result in favor of other, less specific data is problematic and suggests a methodology driven by an attempt to achieve a particular result. *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1293 n. 7 (11th Cir. 2005) ("In evaluating the reliability of an expert's method, however, a district court may properly consider whether the expert's methodology has been contrived to reach a particular result." (citing *Joiner*, 522 U.S. 15 146)).

⁵¹ *Id.*

Similarly, Dr. Harrison cites Lindbohm, M.L., *et al.*, *Spontaneous Abortions Among Rubber Workers and Congenital Malformations in their Offspring*, 9 SCAND. J. WORK, ENV'T, HEALTH 85 (1983),⁵² for its finding that employees of a rubber factory's footwear department were at an increased risk of spontaneous abortion. Dr. Harrison's report fails to mention that the same study found no such association among women employed in the rubber factory's tire department--or in any other profession that researchers examined. Moreover, Dr. Harrison relies on this study despite the authors' conclusion that their observations involving the factory's footwear and tire departments were "contradictory" and that more studies were needed to investigate "the role for solvents in the etiology of spontaneous abortions." *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1248 (11th Cir. 2005) (criticizing an expert for drawing "unauthorized conclusions from limited data--conclusions the authors of the study do not make").

Finally, Dr. Harrison cites Axelsson, G. and Molin, I., *Outcome of Pregnancy Among Women Living Near Petrochemical Industries in Sweden*, 17 INTL J. EPIDEMIOLOGY 363 (1988),⁵³ which examined pregnancy outcomes among women residing near several petrochemical plants. Though

⁵² *Id.*

⁵³ *Id.* at 20.

the study found no association between ambient air exposure and increased pregnancy loss, it did observe increased miscarriages among a small subset of women who worked at one petrochemical plant. The study noted, however, that its sample of petrochemical plant employees was small and that the authors were in the process of conducting a second, more extensive study to determine whether work at the plant increased a woman's risk of miscarriage. In the follow-up study, which Dr. Harrison's report fails to mention, the authors found that "[t]he results do not indicate the presence of an increased risk today" among petrochemical plant employees. Axelsson, G. and Rylander, R., *Outcome of Pregnancy in Women Engaged in Laboratory Work at a Petrochemical Plant*, 16 AM. J. INDUS. MEDICINE 539 (1989). Dr. Harrison's failure to acknowledge this result undermines his reliability.

5. *Summary*

In light of the Court's examination of the studies cited by Dr. Harrison, it is apparent that he relies on a collection of divergent studies that either do not isolate the relevant substances, do not examine the exposure outcome at issue, or do not exhibit statistically significant results. In addition, Dr. Harrison exhibits a willingness to disregard contrary or inconsistent results, even within the studies upon he relies.

Compounding these methodological shortcomings is that, despite citing a body of literature that is inconsistent in both its subject matter and its results, Dr. Harrison fails to present a meaningful analysis in which he reconciles the various studies and explains their relevance to the facts of this case. Instead of explaining how he used the literature to reach his conclusion, Dr. Harrison's report simply lists a number of studies, summarizes their findings (occasionally omitting results that undermine his position), and states a conclusion. Moreover, although Dr. Harrison's report states that he "evaluate[d] all the data based upon recognized scientific factors (the Bradford Hill criteria)," it provides no actual Bradford Hill analysis. *See Burst v. Shell Oil Co.*, No. CIV.A. 14-109, 2015 WL 3620111, at *5 (E.D. La. May 9, 2015) (excluding Dr. Harrison's general causation opinion on whether benzene, as a component of gasoline, can cause AML when Dr. Harrison's "report exhibit[ed] no application of the methodology he state[d] he applied"); *Mallozzi v. EcoSMART Techs., Inc.*, No. 11-CV-2884 SJF ARL, 2013 WL 2415677, at *5 (E.D.N.Y. May 31, 2013) (criticizing an expert for simply stating that he applied the Bradford Hill criteria without discussing his analysis). There is no evidence that he considered, for example, strength of association, replication of findings, specificity of association, or any of the other criteria that epidemiologists use to draw causal inferences in their academic and

professional work. *See Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997) (noting that, under *Daubert*, a district court must "satisfy [itself] that the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting").

Plaintiff resists this conclusion by noting that animal studies have found an association between benzene exposure and spontaneous abortion.⁵⁴ Other than Dr. Harrison's unsupported assurance that he "considered all relevant data, including . . . animal data,"⁵⁵ there is no evidence that Dr. Harrison considered the studies cited in plaintiff's brief. Moreover, even if Dr. Harrison had reviewed this literature, the Fifth Circuit has noted "the very limited usefulness of animal studies when confronted with questions of toxicity." *Brock*, 874 F.2d at 313. Without any analysis demonstrating how animal study findings can predict exposure outcomes in humans, the studies cited by plaintiff "furnish[] at best speculative support for [plaintiff's] causation theory." *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996).

For these reasons, the Court finds Dr. Harrison's methodology unreliable and grants defendants' motion to exclude Dr. Harrison's general causation opinion.

⁵⁴ R. Doc. 44 at 11.

⁵⁵ Dr. Harrison Report at 4.

C. Dr. Bearer

The Court turns to plaintiffs' second expert, neonatologist Dr. Bearer. As to general causation, Dr. Bearer states: "there exists a cause and effect relationship between . . . exposures to one or more of the following chemicals: benzene, hydrogen sulfide, toluene, xylene, heptane, and hexane" and "fetal demise."⁵⁶ Dr. Bearer bases this conclusion on her review of "medical and scientific literature . . . relating to the above identified toxins, workplace, and/or adverse reproductive outcomes."⁵⁷ Specifically, Dr. Bearer's report cites 19 epidemiological studies, each of which also appears in Dr. Harrison's report.⁵⁸ Besides briefly summarizing each study, Dr. Bearer does not reveal any details of her analytical process.

After reviewing Dr. Bearer's report and the materials upon which she relies, the Court finds Dr. Bearer's opinion inadmissible because it too is unreliable. As an initial matter, the Court notes that Dr. Bearer does not identify any literature to support her opinion that is not also cited by Dr. Harrison.⁵⁹ The Court has already found these studies inadequate to reliably

⁵⁶ R. Doc. 32-5 at 3. ("Dr. Bearer Report").

⁵⁷ *Id.*

⁵⁸ *Id.* at 4; R. Doc. 44-10 at 2.

⁵⁹ Indeed, the Court notes that Drs. Harrison's and Bearer's literature reviews are, in most respects, identical, which raises questions about how much original analysis

support a general causation opinion, and Dr. Bearer's reliance on them is defective for the same reasons.

Dr. Bearer's failure to explain her methodology is problematic as well. Like Dr. Harrison, Dr. Bearer provides no analysis in which she reconciles contradicting results within the scientific literature. Nor does she offer any explanation for why the studies upon which she relies support her conclusion, despite their differences with the facts of this case. Indeed, the only mention that Dr. Bearer makes of her analytical approach appears in a single sentence in her expert report: "I will testify with reasonable professional certainty, *relying on methodologies that are generally accepted in my fields of speciality* that there exists a cause and effect relationship between [plaintiff's] exposure . . . and her fetal demise."⁶⁰ Without some explanation of what these methodologies are or how she applied them to the scientific literature, Dr. Bearer's opinion is conclusory *ipse dixit*.

Accordingly, the Court grants defendants' motion to exclude Dr. Bearer's general causation opinion because it is unreliable.

actually underlies each expert's opinion. *See Burst*, 2015 WL 362011 at *5 ("[T]o the extent Dr. Harrison relies on Dr. Infante' report and the studies cited therein, his opinion is inadmissible because it reflects no original analysis or evaluation of Dr. Infante's methodology or the studies upon which he relies.").

⁶⁰ Dr. Bearer Report at 3 (emphasis added).

D. Dr. Waters

Plaintiff's final general causation expert is Dr. Waters, a medical doctor board certified in anatomic, clinical and pediatric pathology, and nuclear medicine. In her expert report, Dr. Waters opines that "increasing benzene is associated with decreased growth of head circumference and weight,"⁶¹ two anomalies observed in plaintiff's fetus. The reported basis for this conclusion is Dr. Waters' review of "studies regarding reproductive health and pregnancy outcome adverse effects of petrochemical exposure [sic]."⁶² Specifically, Dr. Waters cites five epidemiological studies, which she describes as "a small sample" of the relevant literature.⁶³

As an initial matter, the Court notes that although plaintiff--the party offering Dr. Waters' expert testimony--bears the burden of establishing the reliability of Dr. Waters' methodology, she has presented no meaningful opposition to defendants' motion to exclude.⁶⁴ Though plaintiff's opposition

⁶¹ R. Doc. 32-8 at 12. ("Dr. Waters Report").

⁶² *Id.* at 11.

⁶³ *Id.*

⁶⁴ Plaintiff criticizes defendants for questioning her experts' methodologies, rather than conducting their own occupational exposure studies. R. Doc. 44 at 9 ("Ironically, Defendants admit they never performed any studies on benzene and the effects in pregnant women on the fetus."). But the burden is on plaintiff to establish whether her experts' general causation testimony meets the requirements of Federal Rule of Evidence 702. *See Moore*, 151 F.3d at 276 ("[T]he party seeking to have the

memorandum addresses defendants' arguments against Drs. Harrison and Bearer, it is silent on defendants' challenge to Dr. Waters' reliability. Moreover, a review of Dr. Waters' report and the studies cited therein reveals that the studies upon which Dr. Waters relies do not reliably support or do not otherwise "fit" her conclusion. Thus, neither plaintiff nor Dr. Waters have demonstrated the admissibility of Dr. Waters' proffered expert testimony.

One shortcoming in Dr. Waters' methodology is that she relies on studies that focus on solvents as a class, rather than on the specific substances to which plaintiff was allegedly exposed. For instance, Dr. Waters cites Khattak, S., *et al.*, *Pregnancy Outcome Following Gestational Exposure to Organic Solvents*, 281 J. AM. MEDICAL ASS'N 1106 (1999),⁶⁵ for its observation of an association between maternal exposure to organic solvents and developmental malformations. Importantly, the workers in that study were potentially exposed to a wide range of solvents, including phenols, trichloroethylene, vinyl chloride, acetone, and other solvents not at issue in this case. This is problematic because--as Dr. Waters's report fails to note--the study specifically warned against automatically ascribing its observations to any

district court admit expert testimony must demonstrate that the expert's findings and conclusions are based on the scientific method, and, therefore, are reliable."). Plaintiff cannot carry this burden by simply questioning defendants' own research practices.

⁶⁵ *Id.* at 10.

particular substance: "[O]rganic solvents, although traditionally clustered together, are a diverse group of compounds that should not be expected to cause similar patterns of reproductive toxic effects."

Another shortcoming is that, like Drs. Harrison and Bearer, Dr. Waters relies without elaboration or explanation on a study that examines the risk of spontaneous abortion, rather than the later-stage pregnancy loss that plaintiff suffered. *See* Ng, T., *et al.*, *Risk of Spontaneous Abortion in Workers Exposed to Toluene*, 49 BRITISH J. INDUS. MEDICINE 804 (1992) (finding association between spontaneous abortion and specific exposure to toluene).⁶⁶ Because Dr. Waters fails to explain how this study is relevant, despite its inconsistency with the facts of this case, her citation to it does not prove that a reliable methodology underlies her general causation opinion.

A third methodological defect is that Dr. Waters' report cherry-picks data and fails to explain results that contradict her conclusion. For example, Dr. Waters cites Snijder, C., *et al.*, *Occupational Exposure to Chemicals and Fetal Growth: The Generation R Study*, 27 HUMAN REPRODUCTION 910 (2012),⁶⁷ in support of her general causation opinion. Dr. Waters' report fails to note, however, that though the study found statistically significant

⁶⁶ *Id.* at 11.

⁶⁷ *Id.* at 10.

associations involving other chemical categories, it found no association between exposure to organic solvents--the category containing benzene--and reduced fetal growth. That Dr. Waters fails to discuss this pertinent finding in her report casts doubt on the reliability of her methodology.

Finally, Dr. Waters relies upon certain studies even though the study's authors were unwilling to reach a causal conclusion. *See Joiner*, 522 U.S. at 145 (holding that a study did not support an expert's opinion on causation when the study was "unwilling to say that PCB exposure had caused cancer"). In Chevrier, C., *et al.*, *Occupational Exposure to Organic Solvent Mixtures During Pregnancy and the Risk of Non-Syndromic Oral Clefts*, 63 OCCUPATIONAL ENVTL MEDICINE 617 (2006),⁶⁸ researchers observed an association between maternal exposure to petroleum products and non-syndromic oral clefts. Researchers noted, however, that the number of women who were exposed only to petroleum solvents was very small and that "the risk may thus be due to the simultaneous exposure to both types of organic solvents, chlorinated and petroleum." Because, as one of plaintiff's other medical experts acknowledged in his deposition,⁶⁹ plaintiff was not exposed to chlorinated solvents, this study cannot reliably support Dr. Waters' opinion

⁶⁸ *Id.* at 11.

⁶⁹ R. Doc. 53-1 at 3-4.

that the type of exposure alleged by plaintiff can cause oral clefts in the general population.

Though Dr. Waters' report states that her brief literature review "represent[s] a small sample of the studies regarding reproductive health and pregnancy outcome adverse effects of petrochemical exposure," there is no evidence that Dr. Waters reviewed any studies other than the five cited in her report in forming her opinion. Further, Dr. Waters' report provides no indication that Dr. Waters applied the Bradford Hill criteria or any other accepted methodology to the applicable literature. Without any explanation of Dr. Waters' methodology or application of her analytical methods to the literature, the report does not provide a reliable basis for Dr. Waters' opinion. *See Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (noting that an expert's mere "assurances that he has utilized generally accepted scientific methodology is insufficient" to establish his reliability).

Finally, even if the Court's review of the literature revealed a single study that could plausibly support Dr. Waters' opinion,⁷⁰ the majority of studies

⁷⁰ Slama, R., *et al.*, *Maternal Exposure to Airborne Benzene and Intrauterine Growth*, 117 ENVTL. HEALTH PERSP., 1313 (2009), observed an association between maternal exposure to benzene and reduced birth weight and head circumference during pregnancy and at birth. Moreover, unlike most of the other studies upon which plaintiff's experts rely, this study isolated the effects of benzene and measured exposure levels using diffusive air samplers. The Court notes, however, that other fetal growth studies have reached the opposite result. Estarlich, M., *et al.*, *Residential Exposure to*

either do not fit Dr. Waters' conclusion or have no apparent connection to this case beyond conclusory *ipse dixit*. See *Knight*, 482 F.3d at 355 ("Even if one of the studies relied on by [the expert] provided a plausible basis for general causation, the district court, after weighing the 'reliability' and 'relevance' of such evidence, finding one or the other lacking, could still reach the conclusion that the evidence was inadmissible."). Under *Daubert*, the Court must evaluate the expert's underlying methodology to determine whether it is reliable. The Court cannot simply accept an otherwise deficient methodology because there is a scintilla of material that might arguably support the expert's ultimate conclusion. This is particularly true here because "[i]t is important that a study be replicated in different populations and by different investigators before a causal relationship is accepted by epidemiologist and other scientists." Reference Manual at 604.

Accordingly, the Court finds Dr. Waters' methodology unreliable and grants defendants' motion to exclude her general causation opinion.

Because the Court excludes the general causation opinions of Drs. Harrison, Bearer, and Waters, and there is no other general causation evidence

Outdoor Air Pollution During Pregnancy and Anthropometric Measures at Birth in a Multicenter Cohort in Spain, 119 ENVL. HEALTH PERSP., 1333 (2011), for example, found no significant relationship between benzene levels and reduced fetal growth. Given these contradictory studies, the Slama study currently provides only an "inferential starting point" for finding a causal relationship. *LeBlanc* 39 F. App'x at 99.

in this case, the Court need not reach the experts' specific causation opinions or defendants' argument against the methodology underlying those opinions. *See Knight*, 482 F.3d at 351 (stating that a court may admit specific causation evidence only after the plaintiff has produced admissible evidence on general causation).

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS defendants' motion to exclude Drs. Harrison, Bearer, and Waters.

New Orleans, Louisiana, this 4th day of February, 2016.



SARAH S. VANCE
UNITED STATES DISTRICT JUDGE