IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

JOSELIN BARRERA, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. N15C-10-118 VLM
	)	
MONSANTO COMPANY,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Submitted: February 21, 2019
Decided: May 31, 2019

Upon Defendant's Daubert Motion Regarding General Causation,
GRANTED, in part, and **DENIED, in part.**

Upon Defendant's Motion for Summary Judgment Regarding Causation,
DENIED.

Upon Plaintiffs' Daubert Motion to Strike Certain Opinions of Defendant's Expert Witnesses,
DENIED.

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MEDINILLA, J.

I. INTRODUCTION

Plaintiffs Joselin Barrera, Judi Fitzgerald, and Elias de la Garza ("Plaintiffs") filed claims alleging their cancer was caused by exposure to Defendant Monsanto Company ("Monsanto")'s glyphosate-based herbicide product, more commonly known as Roundup. Monsanto moves under Delaware Rule of Evidence 702 to have Plaintiffs' experts' opinions excluded for failure to satisfy *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[1] and for summary judgment under Superior Court Civil Rule 56. Plaintiffs, conversely, move to strike certain opinions of Monsanto's expert witnesses under *Daubert*. After considering the parties' written submissions, supplemental submissions, and oral arguments, for the reasons stated below, Defendant's *Daubert* Motion is **GRANTED**, in part, and **DENIED**, in part, Defendant's Motion for Summary Judgment is **DENIED**, and Plaintiffs' *Daubert* Motion to Strike Certain Opinions of Defendant's Expert Witnesses is **DENIED**.

II. FACTUAL AND PROCEDURAL HISTORY

Monsanto manufactures the herbicide Roundup that contains glyphosate as an active ingredient.[2] Monsanto initially discovered glyphosate's herbicidal properties in 1970.[3] Glyphosate became commercially available in 1974 after Monsanto began

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[1] 509 U.S. 579 (1993) [hereinafter *Daubert I*].
[2] *See* Def. Monsanto Co.'s Opening Br. in Support of its *Daubert* and Summ. J. Mots. Regarding General Causation at 6 [hereinafter Def.'s Opening Br.].
[3] Compl. ¶ 20.

marketing it in its products, under the brand name Roundup.[4] By 2013, glyphosate was the most widely used herbicide and Monsanto is its leading producer.[5] Glyphosate-based herbicides ("GBHs") are utilized across the country to control weeds in agricultural and non-agricultural settings.[6] A number of studies have been conducted for glyphosate to determine its potential risk to human and environmental health.[7] The evaluation of glyphosate's human carcinogenic potential has included a review of epidemiological, animal carcinogenicity, and genotoxicity studies.[8]

Non-Hodgkin Lymphoma ("NHL") affects white blood cells called lymphocytes that are a part of the immune system.[9] Of particular significance in this case is whether glyphosate causes a particular type of cancer known as Non-Hodgkin Lymphoma ("NHL") in humans. This issue has sparked litigation across the country.

A. National Procedural History – Multidistrict Litigation ("MDL")

There are hundreds of lawsuits pending across the country in state and federal courts wherein Plaintiffs allege their NHL diagnoses were caused by Monsanto's

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[4] *See* Def.'s Opening Br. at 6; Compl. ¶ 1.
[5] Compl. ¶¶ 1-2.
[6] EPA Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 12 (Dec. 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0528 ("2017 EPA OPP").
[7] *Id.* at 143.
[8] *Id.*
[9] American Cancer Society, *About Non-Hodgkin Lymphoma* at 1-2 (last revised Aug. 1, 2018), https://www.cancer.org/content/dam/CRC/PDF/Public/8717.00.pdf.

herbicides. The MDL controls the federal cases to coordinate and centralize management of these lawsuits. The MDL bifurcated the pretrial proceedings. The first phase is the general causation phase; the second is the specific causation phase. At issue in the present motions is the first phase considering general causation. The general issue in this phase is whether glyphosate may cause NHL in humans at the levels in which humans are generally exposed.

Monsanto and other plaintiffs filed similar motions in the United States District Court in the Northern District of California ("MDL Court"). In March 2018, the MDL Court held a *Daubert* hearing over seven days regarding the experts that are expected to testify in this case.[10] The MDL Court invited the State courts with similar pending litigation to utilize this hearing within their own proceedings. The parties in the case *sub judice* have relied upon the testimony provided at that hearing and submitted the transcripts with their briefs.[11]

In July 2018, the MDL Court issued a lengthy opinion addressing motions that were before it.[12] The MDL Court thoroughly discussed the underlying studies relied upon by the parties' experts, the scientific data provided therein, the expert testimony from the *Daubert* hearing, the experts' deposition testimony, and the experts'

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[10] There were additional experts who testified at the MDL *Daubert* hearing that are not at issue in this proceeding.

[11] Transcripts from the MDL *Daubert* hearing were provided by both parties, and this Court refers to the transcript as a whole, regardless of which party submitted it, as *Daubert* Hearing Tr.

[12] *See generally In re: Roundup Products Liability Litigation*, 2018 WL 3368534 (N.D. Cal. July 10, 2018) [hereinafter *In re Roundup Litig.*].

reports.[13] The Court denied Monsanto's motion for summary judgment after it determined that some Plaintiffs' experts' opinions were admissible under *Daubert*.[14] The MDL Court denied plaintiffs' *Daubert* motion to exclude the testimony of Monsanto's experts, finding that the experts used reliable scientific methodologies and their opinions were admissible.[15]

The MDL Court's opinion was then offered in these proceedings by Plaintiffs in support of their positions. This Court is guided by the MDL Court and the conclusions reached by that Court. As the parties relied upon the testimony provided in the MDL *Daubert* hearing, this Court also defers to the MDL Court's assessment of the science and underlying studies.[16]

B. Delaware Procedural History

Delaware has bifurcated pretrial proceedings consistent with the MDL Court. On March 13, 2018, Monsanto filed these *Daubert* and Summary Judgment Motions Regarding General Causation and its accompanying Opening Brief. On May 10, 2018, Plaintiffs filed their Response in Opposition to Defendant's *Daubert* and Summary Judgment Motion Regarding General Causation and their *Daubert* Motion to Strike Certain Opinions of Defendant's Expert Witnesses. Monsanto filed its

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[13] *See generally In re Roundup Litig.*, 2018 WL 3368534.
[14] *See id.* at *19-29, 36. The MDL Court found that at least some of the expert opinions of four of Plaintiffs' experts were admissible. That Court also held that the opinions of two of Plaintiffs' experts were not admissible. *Id.* at *29-33.
[15] *Id.* at *33-35.
[16] *Id.* at *8-17.

Reply Brief in Support of its Motions and Opposition to Plaintiffs' *Daubert* Motion on May 29, 2018. On June 12, 2018, Plaintiffs' filed their Reply Brief. During the course of these *Daubert* proceedings, both parties have submitted supplemental authority for the Court to consider.[17] The Court heard oral argument on February 18, 2019.[18] The matter is now ripe for review.

III. *DAUBERT* MOTIONS

Plaintiffs have retained six experts to offer opinions regarding general causation. These retained experts are Dr. Beate Ritz, Dr. Dennis Weisenburger, Dr. Christopher J. Portier, Dr. Charles W. Jameson, Dr. Alfred I. Neugut, and Dr. Chadi Nabhan.[19] These experts each opine similarly that glyphosates can cause NHL in humans. Monsanto moves to exclude all of Plaintiffs' experts. Monsanto has retained its own experts, four of whom Plaintiffs seek to exclude—Dr. Jay I. Goodman, Dr. Warren G. Foster, Dr. Jennifer R. Rider, and Dr. Lorelei A. Mucci. Monsanto's experts opine that the scientific evidence does not support a causal

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[17] On June 12, 2018, Monsanto submitted supplemental authority, which included a recent opinion from the Fourth Circuit. On July 16, 2018, Plaintiffs submitted the MDL Court's opinion on the summary judgment and *Daubert* motions. On January 18, 2019, Monsanto provided the Court with two additional pieces of evidence it considered relevant to its briefing. On February 13, 2019, Plaintiffs submitted supplemental authority, which included a meta-analysis of the relevant scientific studies. On February 21, 2019, Plaintiffs submitted additional correspondence discussing the application of *Daubert* in the Third and Ninth Circuit courts.

[18] The *Daubert* briefing schedule and hearing date were modified due to the MDL Court's proceedings.

[19] Plaintiffs have also designated two non-retained experts—Dr. Aaron Blair and Dr. Matthew Ross.

relationship between glyphosate and NHL.

A. *Daubert* Standard

Delaware Rule of Evidence 702 addresses the admissibility of expert testimony, and 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.[20]

This rule is nearly identical to Federal Rule of Evidence 702.[21] In *Daubert*, the Supreme Court interpreted Federal Rule of Evidence 702 and addressed the admissibility of expert testimony.[22] The Delaware Supreme Court has adopted the holdings of *Daubert* and its progeny "as the correct interpretation of Delaware Rule of Evidence 702."[23]

To determine the admissibility of scientific evidence consistent with *Daubert*, the trial judge must determine whether:

> (1) the witness is qualified as an expert by knowledge, skill experience, training or education;

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[20] D.R.E. 702.
[21] *See Tumlinson v. Advanced Micro Devices, Inc.*, 81 A.3d 1264, 1269 (Del. 2013) [hereinafter *Tumlinson II*].
[22] *See generally Daubert I*, 509 U.S. at 579.
[23] *M.G. Bancorporation v. LeBeau*, 737 A.2d 513, 522 (Del. 1999).

(2) the evidence is relevant;
(3) the expert's opinion is based upon information reasonably relied upon by experts in the particular field;
(4) the expert testimony will assist the trier of fact to understand the evidence or to determine a fact in issue; and
(5) the expert testimony will not create unfair prejudice or confuse or mislead the jury.[24]

A trial judge serves as a gatekeeper to determine if the expert testimony is both relevant and reliable.[25] In doing so, a judge must decide "whether an expert's testimony 'has a reliable basis in the knowledge and experience of [the relevant] discipline.'"[26] While acting as a gatekeeper and determining the reliability of the expert testimony, the trial court should consider the following non-exhaustive factors:

(1) whether a theory or technique has been tested;
(2) whether it has been subjected to peer review and publication;
(3) whether a technique had a high known or potential rate of error and whether there are standards controlling its operation; and
(4) whether the theory or technique enjoys general acceptance within a relevant scientific community.[27]

This list of factors is not a definitive checklist.[28] The *Daubert* analysis focuses on "the principles and methodology used in formulating an expert's testimony, not

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[24] *Bowen v. E.I. DuPont de Nemours & Co., Inc.*, 906 A.2d 787, 795 (Del. 2006).
[25] *See Tumlinson II*, 81 A.3d at 1269 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999)).
[26] *Bowen*, 906 A.2d at 794 (quoting *LeBeau*, 737 A.2d at 523).
[27] *Id.* (quoting *Daubert I*, 509 U.S. at 590-94).
[28] *Scaife v. Astrazeneca LP*, 2009 WL 1610575, at *14 (Del. Super. June 9, 2009) (quoting *Kumho Tire*, 526 U.S. at 150) (internal quotations omitted).

on the expert's resultant conclusions."[29] The trial judge must assess "whether the reasoning or methodology underlying the testimony is scientifically valid and…whether that reasoning or methodology properly can be applied to the facts in issue."[30]

The Delaware Supreme Court has explained that "an expert's methodology must be not only reliable intrinsically but also be reliably applied to the facts of the specific case."[31] The evidence must have "a valid scientific connection to the pertinent inquiry as a precondition to admissibility,"[32] which is described as the "fit" requirement.[33] As to general causation, the inquiry is "whether a substance is capable of causing a particular injury or condition in the general population."[34] An expert's opinions "cannot be based simply on the *ipse dixit* of the expert."[35] The burden of establishing that expert testimony is admissible is on the party proffering it by a preponderance of the evidence.[36]

Albeit dense information, the Court is compelled to provide an overview of

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[29] *Bowen*, 906 A.2d at 794 (citing *Daubert I*, 509 U.S. at 595) (internal quotations omitted).
[30] *Daubert I*, 509 U.S. at 592-93.
[31] *Scaife*, 2009 WL 1610575, at *15 (quoting *General Motors Corp. v. Grenier*, 2009 WL 267665, at *4 (Del. Feb. 4, 2009)).
[32] *In re Asbestos Litig.*, 911 A.2d 1176, 1199 (Del. Super. 2006) (quoting *Daubert I*, 509 U.S. at 592).
[33] *Id.*
[34] *Smith v. Benjamin Moore & Co.*, 2012 WL 2914219, at *2 (Del. Super. July 18, 2012) (quoting *Georgia-Pacific Corp. v. Bostic*, 320 S.W.3d 588, 595 (Tex. App. 2010)).
[35] *Minner v. American Mortg. & Guar. Co.*, 791 A.2d 826, 839 (Del. Super. 2000) (citing *General Electric Company v. Joiner*, 522 U.S. 136, 146 (1997)).
[36] *Scaife*, 2009 WL 1610575, at *15 (citing *Bowen*, 906 A.2d at 795); *see Minner*, 791 A.2d at 843.

the general concepts and science applicable to the experts' opinions to better explain this Court's determination under *Daubert*.

B. Epidemiology

1. Epidemiology Overview and Bradford-Hill Criteria

Epidemiology "is the science of the relationship between human behaviors and patterns, causes, and effects of diseases across the population."[37] It focuses on general causation, at issue in these motions.[38] It is common that "plaintiffs find epidemiological studies indispensable in toxic tort cases when direct proof of causation is lacking."[39] General causation considers the possibility that a certain exposure caused a certain harm, not the likelihood that it did.[40] If epidemiology is being offered to support general causation, "a less stringent standard is, by definition, weaker but potentially probative."[41] The burden is not on the plaintiff to "find a flawless, all-inclusive epidemiological study mirroring their precise circumstances."[42] A plaintiff does not have to support her general causation case with epidemiology evidence as a matter of law.[43]

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[37] *Tumlinson v. Advanced Micro Devices, Inc.*, 2013 WL 7084888, at *4 (Del. Super. Oct. 15, 2013), *aff'd* 81 A.3d 1264 (Del. 2013) [hereinafter *Tumlinson I*].
[38] *Id.* (citation omitted).
[39] *Id.* (quotation and citation omitted).
[40] *Id.* at *5.
[41] *Id.* at *6 (differentiating between epidemiology being offered to support specific causation and general causation).
[42] *Tumlinson*, 2013 WL 7084888, at *7 (citation omitted).
[43] *In re Asbestos Litig.*, 911 A.2d at 1209.

Epidemiology demonstrates an association, after which epidemiologists rely on what is known as the Bradford-Hill criteria to assess whether a causal relationship can be inferred from that association.[44] The Bradford-Hill factors include: "1) temporal relationship, 2) strength of the association, 3) dose-response relationship, 4) replication of the findings, 5) biological plausibility, 6) consideration of alternative explanations, 7) cessation of exposure, 8) specificity of the association, and 9) consistency with other knowledge."[45] Evidence such as animal studies, *in vivo* studies, *in vitro* studies, toxicology, and case studies "can be used together to show causation."[46] An epidemiologist's methods used "to form an opinion as to causation substantially rely on the expert's judgment in selecting and weighing her sources."[47] In order to establish reliability, the expert must "clearly define her methodology and application."[48] In the epidemiology field, an analysis of the Bradford-Hill criteria is a generally accepted method of evaluating scientific evidence.[49] Of particular importance in this case is how the experts weighed the

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[44] *Tumlinson I*, 2013 WL 7084888, at *9; *In re Roundup Litig.*, 2018 WL 3368534, at *7 (explaining when epidemiologists utilize the Bradford Hill criteria to assess causation).
[45] *Tumlinson I*, 2013 WL 7084888, at *9 (outlining the Bradford Hill factors and explaining that they are not all-inclusive and only establish a framework to establish causation) (citation omitted).
[46] *Id.*
[47] *Id.* at *6.
[48] *Id.*
[49] *See In re Roundup Litig.*, 2018 WL 3368534, at *18 (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) [hereinafter *Daubert II*]; *Lust By & Through Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 597 (9th Cir. 1996)).

Bradford-Hill criteria and whether these assessments are reliable.[50]

Here, the parties disagree as to whether statistical significance is a threshold before applying the Bradford-Hill criteria. Monsanto argues a statistically significant association must be shown in the epidemiology before experts can consider the Bradford-Hill factors, relying on *Tumlinson I* and *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*,[51] and contends Plaintiffs do not meet this threshold requirement. Plaintiffs argue that statistical significance is not required before conducting the Bradford-Hill analysis. Regardless, Plaintiffs contend that because the epidemiology here represents a statistically significant association, their experts appropriately proceeded to conduct the Bradford-Hill analysis on the issue of causation.

This Court is guided by the Superior Court in *Tumlinson I* that discusses epidemiology and the requirements of admissibility of evidence to establish general causation.[52] That Court looked to other jurisdictions to determine the standard for the admissibility of epidemiology opinions under *Daubert* in Delaware.[53] In analyzing the admissibility of the proffered expert's opinion on epidemiological studies, the Court stated that "the first question is whether the foundational study

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[50] *In re Roundup Litig.*, 2018 WL 3368534, at *18.
[51] 858 F.3d 787 (3d Cir. 2017) [hereinafter *In re Zoloft*].
[52] *See Tumlinson I*, 2013 WL 7084888, at *4-10 (finding the experts' opinions were unreliable under *Daubert* and inadmissible). The Delaware Supreme Court affirmed the trial court's exclusion of the expert testimony as unreliable. *See Tumlinson II*, 81 A.3d at 1270-73.
[53] *See Tumlinson I*, 2013 WL 7084888, at *4-6.

shows a statistically significant association."[54] The *Tumlinson I* Court then provides that "a study must demonstrate some positive association in order to have value as part of a larger meta-analysis."[55] In other jurisdictions, including the Third Circuit in *In re Zoloft*, statistical significance is not a threshold requirement before an expert may conduct the Bradford-Hill analysis.[56] It stated:

> A causal connection may exist despite the lack of significant findings, due to issues such as random misclassification or insufficient power. Conversely, a causal connection may not exist despite the presence of significant findings. If a causal connection does not actually exist, significant findings can still occur due to, *inter alia*, inability to control for a confounding effect or detection bias. A standard based on replication of statistically significant findings obscures the essential issue: a causal connection....Despite the problems with treating statistical significance as a magic criterion, it remains an important metric to distinguish between results supporting a true association and those resulting from mere chance. Discussions of statistical significance should thus not understate or overstate its importance.[57]

The Third Circuit did not establish a bright-line rule requiring statistical significance to prove causality.[58] This Court agrees. Even if statistical significance

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[54] *Tumlinson I*, 2013 WL 7084888, at *10 (citing *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 220 (3d Cir. 1999)).
[55] *Id.*
[56] *See In re Zoloft*, 858 F.3d at 794 (noting that the District Court rejected the argument "that the existence of a statistically significant, replicated result is a threshold issue before an expert can conduct the Bradford-Hill analysis" and did not require a threshold showing of statistical significance); *In re Joint Eastern & Southern Dist. Asbestos Litig.*, 52 F.3d 1124, 1134 (2d Cir. 1995) ("We believe that it would be far preferable for the district court to *instruct* the jury on statistical significance and then let the jury decide whether many studies over the 1.0 mark have any significance in combination."). *But see Tumlinson I*, 2013 WL 7084888, at *6 ("It also makes sense to require that the entire confidence interval show a positive association—a relative risk over 1.0—to demonstrate that there is a positive association expected at least 95% of the time.").
[57] *In re Zoloft*, 858 F.3d at 793 (citations omitted).
[58] *Id.*

was a threshold requirement here, Plaintiffs' experts rely on various studies, some that show statistically significant associations or positive associations. Thus, Plaintiffs' experts have sufficiently demonstrated a basis for evaluations of the Bradford-Hill criteria.

2. Case-Control Studies, Meta-Analyses, and Cohort Studies

The parties' experts rely on scientific evidence, including case-control studies, meta-analyses, and cohort studies. And the science gets denser.

Case-control studies involve subjects that are included based on their disease status.[59] The study includes subjects who have the disease and those who do not.[60] A pooled analysis combines the raw data from multiple studies and examines the data as a single dataset.[61] The parties' experts here relied upon multiple case-control studies.[62]

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[59] Pls.' Ex. 5, Expert Report of Dr. Beate Ritz, M.D., Ph.D. in Support of General Causation on Behalf of Plaintiffs at 2 [hereinafter Dr. Ritz Report].

[60] *Id.* at 2-3.

[61] *Id.* at 6.

[62] The following is an overview of some, but not all, of the studies reviewed by the experts. The McDuffie (2001) study was a case-control study from Canada. Pls.' Ex. 15, A.J. De Roos, et al., *Integrative Assessment of Multiple Pesticides as Risk Factors for Non-Hodgkin's Lymphoma Among Men*, 60 Occup. Environ. Med. 1 (2003) [hereinafter De Roos (2003)]. In this study, NHL diagnoses occurred between 1991 and 1994. *Id.* at 1156. There were 51 cases of NHL exposed to glyphosate and 133 controls exposed to glyphosate. *See id.* at 1158. In order to compute the odds ratios and the 95% confidence intervals, a conditional logistic regression was utilized. *Id.* at 1157. The overall adjusted odds ratio for glyphosate was reported at 1.2 with a 95% confidence interval of 0.83 to 1.74. *Id.* at 1158. Hereinafter, the 95% confidence interval will be provided as the following: odds ratio (lower point-higher bound). The odds ratio was adjusted for other medical variables, including a history of certain diseases, allergy desensitization shots, a positive family history of cancer, age, and province of residence, but not for the use of other pesticides. *See id.* Additionally, the study reported that for zero to two days of exposure to glyphosate per year the

Case-control studies report odds ratios "as the measure of association between the variables the investigators are studying."[63] An odds ratio is a measure of an

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odds ratio was 1.00 (0.63-1.57). *Id.* at 1161. The study stated that when there was glyphosate exposure of more than two days per year, the odds ratio was 2.12 (1.20-3.73). *Id.* Overall, the study reported that its results supported prior findings of an association between NHL and exposure to certain pesticides. *Id.* at 1162.

The De Roos (2003) study was a pooled analysis of three case-controlled studies. Pls.' Ex. 15, A.J. De Roos, et al., *Integrative Assessment of Multiple Pesticides as Risk Factors for Non-Hodgkin's Lymphoma Among Men*, 60 Occup. Environ. Med. 1 (2003) [hereinafter De Roos (2003)]. De Roos (2003) analyzed the effect of exposure to pesticides on the incidence of NHL, focusing only on men. *Id.* at 1. In De Roos (2003), the authors examined 47 different pesticides, including insecticides and herbicides. *Id.* at 2. The study utilized both standard logistic regression and hierarchical regression to calculate the odds ratios and estimate the risk associated with each pesticide. *Id.* Using the logistic regression model, the odds ratio for glyphosate was 2.1 (1.1-4.0). *Id.* at 5. Using the hierarchical regression model, the odds ratio for glyphosate was 1.6 (0.9-2.8). *Id.* These effect estimates adjusted for the use of all other pesticides in the study. *Id.*

The Eriksson (2008) study assessed exposure to pesticides and NHL, with the cases of NHL collected between 1999 and 2002. Pls.' Ex. 19, Erik Eriksson, et al., *Pesticide Exposure as Risk Factor for Non-Hodgkin Lymphoma Including Histopathological Subgroup Analysis*, 123 Int. J. Cancer 1657 (2008) [hereinafter Eriksson (2008)]. Under the univariate model, the authors reported glyphosate exposure at an overall odds ratio of 2.02 with a 95% confidence interval of 1.10 to 3.71. *Id.* at 1658, 1659. For those exposed to glyphosate for ten days or less, the odds ratio was reported at 1.69 (0.70-4.07). *Id.* at 1659. For greater than ten days of exposure to glyphosate, the odds ratio was 2.36 (1.04-5.37). *Id.* When there was greater than ten years of latency, the odds ratio was 2.26 (1.16-4.40). *Id.* For those who developed cancer less than 10 years after exposure, the odds ratio was 1.11 (0.24-5.08). *Id.* A multivariate analysis was performed, and yielded an odds ratio of 1.51 (0.77-2.94) for glyphosate. *Id.* at 1661. Eriksson (2008) concluded that the results strengthened its previous indication "of an association between glyphosate and NHL." *Id.* at 1662.

The North American Pooled Project ("NAPP") (2015) study is a pooled analysis of three case-control studies that were included in McDuffie (2001) and De Roos (2003). *Daubert* Hearing Tr. at 218:25-219:5. The results of this study are not published in a peer-reviewed journal. NAPP (2015) assessed the associations between exposure to glyphosate and NHL. Pls.' Ex. 25, Manisha Pahwa, et al., *An Evaluation of Glyphosate Use and the Risk of Non-Hodgkin Lymphoma Major Histological Sub-Types in the North American Pooled Project (NAPP)* at 2 (Sept. 21, 2015). The study reported an odds ratio of 1.51 (1.18-1.95) for overall exposure to glyphosate. *See* Pls.' (1) Resp. in Opp. to Def.'s *Daubert* and Summ. J. Mot. Regarding General Causation and (2) *Daubert* Mot. to Strike Certain Opinions of Def.'s Expert Witnesses at 18 [hereinafter Pls.' Answering Br.]; Pls.' Ex. 23. Pahwa, Manisha, et al., *An Evaluation of Glyphosate Use and the Risks of Non-Hodgkin Lymphoma Major Histological Sub-Types in the North American Pooled Project (NAPP)*, International Society for Environmental Epidemiology, (Aug. 31, 2016).

[63] *In re Roundup Litig.*, 2018 WL 3368534, at *8.

association between exposure to an agent, like glyphosate, and a disease, like NHL, that is expressed in quantitative terms.[64] "In a case-control study, the odds ratio is the ratio of the odds that a case (one with the disease) was exposed to the odds that a control (one without the disease) was exposed."[65] If the odds ratio is greater than 1.0, then it indicates an association.[66]

Confidence intervals generally accompany odds ratios. The standard interval—95% confidence interval—sets forth a range of error. The confidence interval provides "a range (interval) within which the risk likely would fall if the study were repeated numerous times."[67] With a 95% confidence interval, the range includes "the results we would expect 95% of the time if samples for new studies were repeatedly drawn from the same population."[68] This confidence interval "means that there is a 95% chance that the 'true' odds ratio value falls within the confidence interval range."[69] The ratio is considered statistically significant "if the lower bound of the confidence interval is greater than one[.]"[70] Statistical significance is used to determine if there is a relationship between certain factors or

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[64] Michael D. Green et al., *Reference Guide on Epidemiology*, in Reference Manual on Scientific Evidence 551, 568 (3d ed. 2011) [hereinafter Reference Manual].
[65] *Id.*
[66] *See In re Roundup Litig.*, 2018 WL 3368534, at *8.
[67] Reference Manual at 573.
[68] *Id.* at 580.
[69] *In re: Zoloft (Sertraline Hydrocloride) Products Liability Litig.*, 2015 WL 7776911, at *2 (E.D. Pa. Dec. 2, 2015).
[70] *Id.*

if the outcome of a study resulted from chance.

Another important concept to epidemiology is known as confounding. "Confounding occurs when another causal factor (the confounder) confuses the relationship between the agent of interest and outcome of interest."[71] An "instance of confounding is when a confounder is both a risk factor for the disease and a factor associated with the exposure of interest."[72] A researcher must determine whether an association between an agent and a disease "is causal or the result of confounding."[73]

Another form of studies is known as meta-analyses. Meta-analyses are used to combine multiple studies' results.[74] "Meta-analysis is a method of pooling study results to arrive at a single figure to represent the totality of the studies reviewed."[75] The studies in a meta-analysis are given different weights, depending on the size of the study populations and other characteristics.[76] Rather than using the raw data like in pooled analyses, meta-analysis uses the "[o]dds [r]atios or [r]ate [r]atios and confidence intervals which were published in the original studies."[77] A rate ratio "compares the incidence rates of disease given an exposure, to the incidence rate of disease among people without the exposure."[78] The experts here also rely on meta-

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[71] Reference Manual at 591 (citation omitted).
[72] *Id.*
[73] *Id.*
[74] *Id.* at 581, n.89.
[75] *Id.* at 607.
[76] Reference Manual at 607.
[77] Dr. Ritz Report at 6.
[78] *Id.* at 4.

analyses to support their opinions, including Schinasi and Leon (2014),[79] Chang and Delzell (2016),[80] and IARC.[81]

Finally, there are cohort studies. A cohort study involves "groups of individuals [that] can be identified who are, have been, or in the future may be differentially exposed to an agent or agents hypothesized to influence the incidence

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[79] Pls.' Ex. 30, Leah Schinasi and Maria E. Leon, *Non-Hodgkin Lymphoma and Occupational Exposure to Agricultural Pesticide Chemical Groups and Active Ingredients: A Systemic Review and Meta-Analysis*, 11 Int. J. Environ. Res. Public Health 4449 (2014) [hereinafter Schinasi and Leon (2014)].

[80] Pls.' Ex. 31, Ellen T. Chang and Elizabeth Delzell, *Systemic Review and Meta-Analysis of Glyphosate Exposure and Risk of Lymphohematopoietic Cancers*, 51 J. of Environ. Science and Health 402 (2016) [hereinafter Chang and Delzell (2016)].

[81] IARC, *Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos, Monograph Vol. 112 on the Evaluation of Carcinogenic Risks to Humans* at 1 (2015), http://monographs.iarc.fr/ENG/Monographs/vol112 /mono112-10.pdf [hereinafter IARC Monograph]. *See generally* IARC, *IARC Monographs on the Evaluation of Carcinogenic Risk to Human Preamble* [hereinafter IARC Preamble]. In 2015, the International Agency for Research on Cancer ("IARC"), a subdivision of the World Health Organization ("WHO"), initiated a working group to examine the association between glyphosate and cancer. This working group created a "Monograph" to evaluate scientific data and studies and determined that glyphosate was "probably carcinogenic to humans." IARC Monograph at 78.

The IARC Monograph (2015), relied upon heavily by Plaintiffs, examined glyphosate exposure and the incidence of cancer in humans. *See generally id.* The IARC discussed numerous cohort studies and case-control studies relating to glyphosate exposure in humans and examined animal studies and other available data. *See generally id.*

The IARC concluded that there is "limited evidence in humans for the carcinogenicity of glyphosate," which means that a "positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence." *Id.* at 78; IARC Preamble at 19-20. As to carcinogenicity in experimental animals, the IARC concluded that there was sufficient evidence, meaning "that a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms" in animal studies. IARC Monograph at 78; IARC Preamble at 20. IARC found overall that glyphosate is probably carcinogenic to humans and labeled glyphosate as a Group 2A agent, which is the classification for when "there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals." IARC Monograph at 78; IARC Preamble at 22.

of occurrence of a disease or other outcome."[82] Here, the cohort study deals with exposure to glyphosate and the incidence of the occurrence of NHL.[83]

In this case, the experts relied upon a number of these various types of studies to formulate their opinions. The MDL Court addressed a number of these studies, explaining the methods used by the authors and their results.[84] The Court has reviewed the epidemiological evidence and the experts' respective reports applicable to this litigation that were presented as exhibits to the pleadings, including the case-control studies, meta-analyses, and cohort study. The Court has also examined the MDL Court's assessment of the underlying epidemiology evidence.

Overall, as to both parties, some of the epidemiology studies suggest an association between glyphosate exposure and NHL, whereas other studies do not.[85]

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[82] Reference Manual at 621.

[83] Monsanto relies on the Agricultural Health Study cohort study ("AHS Cohort") that it argues comports with the *Daubert* factors for reliability to support that there is no association between glyphosate exposure and NHL. Def.'s Ex. 17, Gabriella Andreotti, et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, 110 J. Nat'l Cancer Inst. 1 (published online Nov. 17, 2017) [hereinafter AHS Cohort]. The AHS observed no association between glyphosate use and NHL. *Id.* at 7. This study considered glyphosate use that was reported at enrollment between 1993 and 1997. *Id.* at 2. During that time period, over 57,000 individuals seeking licenses to apply certain pesticides were enrolled. *Id.* The AHS cohort study ascertained use of fifty pesticides, including glyphosate. *Id.* Five years after the enrollment, 63% of the participants completed a follow up phone interview between 1999 through 2005. *Id.* Cancer registries in Iowa and North Carolina provided information about cancer diagnoses of participants. *Id.* The study adjusted for several factors including, but not limited to, age, cigarette smoking status, alcohol drinks per month, and family history of cancer. *Id.*

The AHS cohort reported four rate ratios based on the lifetime days of exposure in regards to glyphosate use and the incidence of NHL. *Id.* at 2, 5. The quartile with the highest number of lifetime days of glyphosate use reported a rate ratio of 0.87 (0.64-1.20). *Id.* at 5.

[84] *See In re Roundup Litig.*, 2018 WL 3368534, at *9-10 (outlining the frequently discussed case-control studies).

[85] *Id.* at *1.

Based on an extensive assessment of the epidemiological studies, the MDL Court found that "[a]ll the studies leave certain questions unanswered, and every study has its flaws."[86] Although confounding of exposure to other pesticides is a concern in the case-control studies, the studies relied upon by the experts adjusted for different confounders to varying degrees.[87]

In sum, "the epidemiology evidence is open to different interpretations, and the potential flaws in the data from the case-control studies and meta-analyses are not overwhelmingly greater than the potential flaws in the data from the [cohort] study."[88] Experts operating on reliable scientific principles could weigh the studies differently "and could conclude that the analyses of the case-control studies support an association between glyphosate exposure and NHL, even if this is not necessarily the best interpretation of the evidence."[89] This Court finds no reasons to disturb the MDL Court's assessment of the merits of the epidemiological studies. Thus, an expert cannot be excluded as unreliable for weighing the case-control studies more favorably than the cohort study.[90]

C. Laboratory Animal Carcinogenicity Studies

Plaintiffs' experts also rely on animal carcinogenicity studies to form their

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[86] *In re Roundup Litig.*, 2018 WL 3368534, at 1.
[87] *Id.* at *13.
[88] *Id.* at *15.
[89] *Id.* (citing *Daubert II*, 43 F.3d at 1317).
[90] *See id.*

opinions on general causation. Monsanto argues that many of Plaintiffs' experts are not qualified to opine about rodent carcinogenicity data.[91] As to the experts that Monsanto contends are qualified, it argues that they are unable to link the animal data results regarding glyphosate and NHL to the human condition.[92] Further, Monsanto contends that the experts' opinions are based upon unsound scientific principles.[93]

The animal carcinogenicity evidence advances a material aspect of Plaintiff's case[94] because the animal bioassays are germane to the biological plausibility factor of the Bradford-Hill analysis.[95] Plaintiffs argue that glyphosate can cause NHL in humans and the animal carcinogenicity studies that demonstrate that glyphosate is carcinogenic in rodents logically advances this argument.[96] These experts do not rely solely upon animal studies to establish general causation. They also discuss epidemiological evidence and mechanistic data. The animal carcinogenicity evidence will assist the trier of fact to understand an issue in this case and has a valid scientific connection to the issues here.[97]

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[91] Def.'s Opening Br. at 22, n.42.
[92] *Id.* at 22-24.
[93] *See id.* at 24-40.
[94] *See Daubert II*, 43 F.3d at 1315. Ensuring that the expert's proposed testimony "is relevant to the task at hand" is known as the "fit" requirement. *Id.* (citations omitted).
[95] *See In re Roundup Litig.*, 2018 WL 3368534, at *15.
[96] *See Tumlinson I*, 2013 WL 7084888, at *9 ("Other forms of evidence including toxicology, *in vivo* studies, *in vitro* studies, animal studies, and case studies can be used to show causation.")
[97] *See In re Asbestos Litig.*, 911 A.2d at 1199 (citations omitted).

D. Mechanistic Data

Plaintiffs also try to submit evidence regarding mechanistic data, including genotoxicity evidence and oxidative stress. This type of evidence involves whether certain chemicals, like glyphosate, can cause changes at the cellular level that could cause cancer.[98] Monsanto argues this type of data does not meet *Daubert*'s "fit" requirement, is not scientifically reliable, and should only be considered when scientifically sound human data is unavailable.[99]

Delaware law does not require that evidence of general causation take the form of epidemiological evidence.[100] Other types of scientific evidence may suffice to establish general causation if it is relevant and reliable.[101] Here, Plaintiffs' experts rely on two studies—Bolognesi (2009) and Paz-y-Mino (2007).[102] Monsanto contends that these studies' methodologies are flawed, and any opinions formed based on reliance on these studies must be excluded. Bolognesi (2009) conducted a cytogenetic biomonitoring study from five regions in Colombia to evaluate genotoxic effect of aerial spraying of glyphosate.[103] This study used both ecological

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[98] *In re Roundup Litig.*, 2018 WL 3368534, at *17.
[99] *See* Def.'s Opening Br. at 40-45.
[100] *In re Asbestos Litig.*, 911 A.2d at 1209.
[101] *Id.*
[102] *See* Pls.' Ex. 73, C. Bolognesi, et al., *Biomonitoring of Genotoxic Risk in Agricultural Workers from Five Colombian Regions: Association to Occupational Exposure to Glyphosate*, 72 J. Toxicology Envtl. Health, Part A 986 (2009) [hereinafter Bolognesi (2009)]; Pls.' Ex. 72, C. Paz-y-Mino, et al., *Evaluation of DNA Damage in an Ecuadorian Population Exposed to Glyphosate*, 30 Genetics and Molecular Biology 453 (2007) [hereinafter Paz-y-Mino (2007)].
[103] Bolognesi (2009) at 988.

and self-reported approaches to characterize exposure to glyphosate, and the authors noted that the ecological method may cause misclassification of exposures.[104] Paz-y-Mino (2007) performed a study to analyze the impact of glyphosate used in aerial spraying in norther Ecuador on the impacted individual's genetic material.[105]

Although epidemiology has been presented by both sides, other types of scientific evidence, such as mechanistic data involving genotoxicity, is relevant to the biological plausibility prong of the Bradford-Hill analysis. This Court finds Plaintiffs' experts' opinions on mechanistic data are relevant and meet *Daubert*'s "fit" requirement. The Court will now consider the admissibility of the experts' opinions.

IV. MONSANTO'S *DAUBERT* MOTION

Before addressing the parties' respective experts, it is important for the Court to reiterate that "*Daubert* permits testimony that is the product of competing principles or methods in the same field of expertise."[106] Further, the courtroom is not intended to be a scientific laboratory and the "judge is not a scientist."[107] The Court's analysis under *Daubert* is focused on the principles and methodologies employed by the experts in creating their opinions, not on the experts'

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[104] Bolognesi (2009) at 995.
[105] Paz-y-Mino (2007) at 456-57.
[106] *In re Asbestos Litig.*, 911 A.2d at 1201 (citing *Heller,* 167 F.3d at 160).
[107] *See id.* at 1199 (citation omitted).

conclusions.[108] The Court's role is to determine that the expert's opinion is sufficiently reliable, will assist the trier of fact to understand the evidence, and will not create unfair prejudice or mislead the jury.[109] The reliability requirement is not a tool for the Court to use to exclude questionably reliable evidence.[110]

A. Dr. Ritz

Dr. Ritz is a Professor of Epidemiology at the UCLA Fielding School of Public Health.[111] Dr. Ritz holds a Ph.D. in epidemiology and an MD.[112] Her primary research interests focus on the health effects of environmental and occupational exposures.[113] There is no dispute that Dr. Ritz is qualified to opine about the epidemiology evidence at issue in this case.

Dr. Ritz opines that Roundup is capable of causing NHL.[114] Dr. Ritz reviewed numerous epidemiologic studies and examined how these studies worked together.[115] The studies she identified included the NAPP, IARC Monograph, Eriksson (2008), and De Roos (2003).[116] Dr. Ritz also evaluated the Bradford-Hill criteria. Proceeding to the Bradford-Hill analysis, she found that the strength

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[108] *See Bowen*, 906 A.2d at 794 (discussing focus of *Daubert* analysis).
[109] *See id.*
[110] *See Tumlinson I*, 2013 WL 7084888, at *2 (quoting *United States v. Velasquez*, 64 F.3d 844, 850 (3d Cir. 1995)).
[111] Dr. Ritz Report at 1.
[112] *Id.*
[113] *Id.*
[114] *Daubert* Hearing Tr. at 95:19-25.
[115] Dr. Ritz Report at 14-15.
[116] *Id.* at 15-23.

criterion was "partially met" given that the meta-analytical effect estimates reflected "a weak to moderate size association."[117] Dr. Ritz found that the dose-response, consistency, and temporality criteria were met.[118]

Dr. Ritz stated that the specificity criterion is difficult to apply in cases like these involving pesticide or herbicide exposure because most people who work with these products are not exposed solely to glyphosate.[119] In terms of biological plausibility, Dr. Ritz concluded that this criterion was met.[120] As to the coherence criterion, Dr. Ritz explained that "there will never be any human experimental evidence for glyphosate toxicity or carcinogenicity...."[121]

Dr. Ritz relied on mechanistic evidence in her report to support the biological plausibility that a causal connection between glyphosate and NHL exists.[122] She noted that two mechanisms—oxidative stress and genotoxicity—have been proposed recently for glyphosate and provided brief summaries of studies that confirm this.[123] Dr. Ritz found that the epidemiologic studies support "an increased risk of NHL with exposure to glyphosate or glyphosate based formulations, including Roundup."[124] Ultimately, Dr. Ritz concluded to a reasonably degree of

[117] Dr. Ritz Report at 23.
[118] *Id.* at 23-24.
[119] *Id.* at 24.
[120] *Id.* at 24-25.
[121] *Id.* at 25.
[122] Dr. Ritz Report at 24-25.
[123] *Id.* at 25.
[124] *Id.*

scientific certainty that glyphosate and glyphosate-based formulations cause NHL.[125]

Monsanto argues that Dr. Ritz has changed her opinion on the epidemiological evidence, after initially relying on reported confounded odds ratio but later distancing herself from the study results because the adjusted data did not show an association between glyphosate and NHL. This goes to the weight of the evidence, not admissibility. While it is true that Dr. Ritz emphasized unadjusted numbers in her report, her analysis also considered adjusted numbers. Some of the meta-analyses relied upon by Dr. Ritz included fully adjusted estimates and some of the studies adjusted for other pesticides.[126]

Dr. Ritz's opinion is relevant to general causation and whether glyphosate can cause NHL in humans at realistic levels to which they are exposed. The principles and methodology underlying Dr. Ritz's opinion are scientifically valid and can be properly applied to this case. Her opinion provides sufficient specificity to satisfy *Daubert*'s testability factor. Also, Dr. Ritz relied upon peer-reviewed studies and literature. She conducted a Bradford-Hill analysis, which is a technique relied upon by epidemiologists to establish causation,[127] and sufficiently articulated her

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[125] Dr. Ritz Report at 25.
[126] *Id.* at 16, 19.
[127] *See Tumlinson II,* 81 A.3d at 1272 (explaining that epidemiologists rely on two methods to establish causation—Bradford-Hill analysis and weight-of-the-evidence analysis).

evaluation methods to establish reliability. Dr. Ritz's opinions on the epidemiology evidence are admissible and her assessment of the Bradford-Hill criteria is admissible to the extent it is limited to her role as an epidemiologist performing this analysis.[128] Dr. Ritz's expert opinion satisfies the *Daubert* requirements for reliability; therefore, her opinion is admissible under D.R.E. 702.

B. Dr. Weisenburger

Dr. Weisenburger is a hematopathologist; a physician and a pathologist that studies diseases of the immune system, blood, and bone marrow, which includes NHL.[129] His specialty includes studying the pathology, subtypes, genetics, epidemiology, causes or etiologies, and clinical features of NHL.[130] Monsanto does not dispute that Dr. Weisenburger is qualified to opine on epidemiology evidence.[131]

Dr. Weisenburger's report first addresses epidemiology in humans by examining six published case-control studies, one cohort study, and three meta-analyses.[132] After his brief review of the epidemiological data, Dr. Weisenburger concluded that the studies provide evidence "for a relationship between glyphosate

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[128] *See In re Roundup Litig.*, 2018 WL 3368534, at *27. Similar to the MDL Court, any "forest plot" from Dr. Ritz's report will not be presented to the jury because it is misleading. *Id.* at *26.
[129] *Daubert* Hearing Tr. at 169:14-18.
[130] *Id.* at 169:19-24. He is also a co-author of De Roos (2003).
[131] *See* Def.'s Opening Br. at 12, n.18. Monsanto argues that Dr. Weisenburger is unqualified to render opinions on rodent bioassay data or mechanistic data. *See id.* at 22, n.42 and 43, n.71.
[132] Pls.' Ex. 10, Expert Report of Dr. Dennis Weisenburger, M.D. in Support of General Causation on Behalf of Plaintiffs at 4-6 [hereinafter Dr. Weisenburger Report].

exposure and risk of NHL…."[133]

He also discusses animal studies, where the carcinogenicity of glyphosate has been tested in rodents, and the mechanisms of carcinogenesis.[134] Dr. Weisenburger concurred with the findings of three animal studies that there were positive findings of carcinogenicity for glyphosate.[135] He further concurred with IARC findings that glyphosates are genotoxic.[136] Dr. Weisenburger conducted a Bradford-Hill analysis and concluded that glyphosate can cause NHL in humans.[137] He opines that glyphosate may cause NHL in humans at exposure levels that people are currently experiencing.[138]

Experts may rely on more than just the epidemiology studies to support their opinions, including animal studies and mechanistic data. As to Dr. Weisenburger's opinion on the epidemiology evidence, this Court finds that Plaintiffs have met their burden of admissibility under *Daubert* and D.R.E. 702.[139] The methodologies underlying his opinions are scientifically valid as supported by his review of the epidemiological studies. Plaintiffs have also met their burden for the admissibility of Dr. Weisenburger's other opinions, including his Bradford-Hill analysis in light

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[133] Dr. Weisenburger Report at 6.
[134] *Id.* at 6-10.
[135] *Id.* at 7.
[136] *Id.* at 8-10.
[137] *Daubert* Hearing Tr. at 207:15-208:2.
[138] *Id.* at 208:11-17.
[139] *See In re Roundup Litig.*, 2018 WL 2268534, at *28 (determining that Dr. Weisenburger's epidemiology opinion was admissible under *Daubert*).

of his interpretation of the underlying epidemiology studies.[140]

Dr. Weisenburger is qualified to render these opinions. His opinion will help the trier of fact understand the evidence and determine the issue of general causation. His testimony is based on sufficient facts and data, results from reliable principles and methodologies, and he has reliably applied the principles and methodologies to this case.[141]

C. Dr. Portier

Dr. Portier earned a Master's degree and Ph.D. in biostatistics from University of North Carolina.[142] His thesis dealt with the design of a "rodent carcinogenicity study to assess the ability of a chemical to cause cancer…."[143] He is a biostatistician who worked a large portion of his career at the National Institute of Environmental Health Sciences and the National Toxicology Program and became the Director of the National Center for Environmental Health in 2010.[144] His subspecialty involves environmental laboratory studies.[145] During his career, he has contributed to risk assessments for IARC.[146]

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[140] *See In re Roundup Litig.*, 2018 WL 2268534, at *29 (holding that the remainder of Dr. Weisenburger's opinion, including his Bradford-Hill analysis, was admissible).
[141] *See* D.R.E. 702.
[142] Def.'s Ex. 7, Expert Report of Dr. Christopher J. Portier in Support of General Causation on Behalf of Plaintiffs at 1 [hereinafter Dr. Portier Report].
[143] *Id.*
[144] *Id.* at 1-3.
[145] *Daubert* Hearing Tr. at 543:5-6.
[146] *See* Dr. Portier Report at 3.

Dr. Portier opines to a reasonable degree of scientific certainty that glyphosate probably causes NHL and that the probability is high.[147] In formulating his opinions, Dr. Portier reviewed epidemiology, toxicology, and mechanisms-of-cancer literature.[148] As to the epidemiology literature, he identified six case-control studies that showed "similar modest increases of associations between glyphosate and NHL."[149] He also reviewed the AHS Cohort. Dr. Portier "concluded that causality is possible, but there's still the possibility of bias, chance, and confounding in these data."[150] He does not believe that bias, chance, and confounding are strong enough to explain the entire association.[151]

Dr. Portier provided his own analysis of the epidemiology evidence, and reached a similar conclusion as the IARC.[152] He reviewed numbers that were adjusted for the use of other pesticides, including the IARC Monograph and a study by Chang and Delzell (2016).[153] He noted studies that were going to be excluded from his evaluation of causation or would only be given little weight in his evaluation.[154] Among the six core studies that he identified,[155] Dr. Portier concluded

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[147] *Daubert* Hearing Tr. at 545:10-13.
[148] *See id.* at 545:1-5.
[149] *Id.* at 545:18-20.
[150] *Id.* at 546:3-5.
[151] *Id.* at 546:8-13.
[152] Dr. Portier Report at 6-18.
[153] *Id.* at 14-15.
[154] *Id.* at 9, 13.
[155] *Id.* at 15. These studies included McDuffie et al. (2001), Hardell et al. (2002), De Roos et al. (2003) and (2005), Eriksson et al. (2008), and Orsi et al. (2009).

that "[t]here is a strong association across the six core studies."[156] When using the most-fully-adjusted numbers, Dr. Portier explained that there was a "modest increase" in NHL with exposure to glyphosate, but that when the six studies were combined they demonstrated "a significant strength of association."[157]

Dr. Portier opines the studies provide a strong association and then performs his Bradford-Hill analysis. He finds, based on two case-control studies and one cohort study, that the biological gradient criterion was supported by a moderate degree.[158] Dr. Portier concluded that the temporal relationship criterion of the Bradford-Hill evaluation is satisfied because exposure came before the onset of cancer.[159] As to the specificity criterion, Dr. Portier concluded that there is little support for this element of the analysis, but also found that it was not needed.[160]

Dr. Portier found that the consistency criterion was satisfied and strong after discussing the six core studies and the Chang and Delzell (2016) meta-analysis that showed similar results to the other studies and lends support that the findings are consistent.[161] He ultimately found that the strength of the observed association criterion was demonstrated by a strong degree.[162]

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[156] Dr. Portier Report at 19.
[157] *Id.*
[158] *Id.* at 74-75, 77.
[159] *Id.* at 75, 77.
[160] *Id.*
[161] Dr. Portier Report at 17-18, 77.
[162] *Id.* at 77.

Dr. Portier additionally evaluated the biological plausibility criterion and found that it showed "very strong" support for causation.[163] In reaching this finding, Dr. Portier evaluated animal carcinogenicity studies and summarized that glyphosate causes cancer in mammals.[164] He further analyzed mechanisms relating to carcinogenicity, including genotoxicity in humans and non-human mammals studies and studies relating to oxidative stress.[165] In conclusion, Dr. Portier opined "[t]here is strong support for biological plausibility in support of a causal association of glyphosate and glyphosate formulations with NHL."[166] As to the evidence in human experimentation criterion, Dr. Portier held there were no studies available.[167] Lastly, he explained that there were no studies available as to the analogy criterion and he does not have a sufficient background to render an opinion in this area.[168]

Monsanto argues that Dr. Portier is not qualified to render epidemiology-based opinions because he is a toxicologist without the requisite specialized knowledge or experience.[169] This Court disagrees. The Court finds that Dr. Portier is qualified to offer opinions regarding epidemiology even though he is not an epidemiologist because he has reviewed epidemiology literature throughout his

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[163] Dr. Portier Report at 77.
[164] *Id.* at 51-52.
[165] *Id.* at 19-74.
[166] *Id.* at 73.
[167] *Id.* at 76, 77.
[168] Dr. Portier Report at 76, 77.
[169] Def.'s Opening Br. at 12, n.18.

career.[170]

Dr. Portier's epidemiology-related opinions and his Bradford-Hill analysis are reliable under *Daubert* and are admissible. Dr. Portier employed sound methodology when reviewing the epidemiology studies and conducting his analysis of the Bradford-Hill criteria, with the exception of his pooling method. Dr. Portier used a pooling method to analyze the results of multiple rodent carcinogenicity studies. Monsanto argues that Dr. Portier's pooling method is a "novel technique" and he engaged in selective pooling to create statistically significant results.[171] To determine whether Dr. Portier's pooling method is rooted in science, the Court looks to the non-exhaustive factors provided by *Daubert*. First, there is no evidence that this method has been tested. Next, his pooling method does not appear to have been subject to peer review. Also, his method has not gained general acceptance in the scientific community.[172] Because Dr. Portier's pooling method is not derived from the scientific method, it is not reliable under *Daubert*.[173] Thus, Dr. Portier's opinions regarding animal carcinogenicity are admissible with the exception of the pooled

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[170] *See* D.R.E. 702 (providing that expert may be qualified based on skill, experience, or training).
[171] *See* Def.'s Opening Br. at 29-34.
[172] *Daubert* Hearing Tr. 638:2-13. Dr. Portier testified that he might be the only one who has performed this pooling analysis, suggesting that it is not generally accepted in the scientific community. Dr. Portier contended that another scientist used a similar pooling method, but Monsanto noted the differences in the pooling analysis in the other studies. *See id.* at 635:19-636:16.
[173] *See Bowen*, 906 A.2d at 794 (citing *Daubert I*, 509 U.S. at 590).

analysis.[174] His mechanistic data opinions are admissible because the methodologies relied upon to form his opinions are grounded in science.[175] Monsanto can utilize cross-examination and presentation of contrary evidence to attack the evidence presented through Dr. Portier.[176]

D. Dr. Jameson

Dr. Jameson received a Ph.D. in Organic Chemistry and has worked for the National Institutes of Health's National Cancer Institute ("NCI") on the Rodent Bioassay program and has contributed to hundreds of bioassay studies.[177] He is an environmental toxicologist and has served as a member of IARC working groups throughout his career.[178]

Before discussing the epidemiology evidence, Dr. Jameson summarized the IARC Monograph and the working group's evaluation.[179] In addition to summarizing the IARC Monograph, he outlined the criteria he used for his "hazard based assessment of glyphosate and/or glyphosate-based formulations" and explained that it "is the same as defined and characterized by IARC."[180] His opinion emphasized significant reliance on the IARC Monograph and his decision to perform

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[174] *See In re Roundup Litig.*, 2018 WL 3368534, at *24.
[175] *See Tumlinson I*, 2013 WL 7084888, at *2.
[176] *See Daubert I*, 509 U.S. at 596.
[177] Pls.' Ex. 8, Expert Report of Dr. Charles W. Jameson, Ph.D. in Support of General Causation on Behalf of Plaintiffs at 1 [hereinafter Dr. Jameson Report].
[178] *See id.* at 1, 4.
[179] *See id.* at 4-8.
[180] *Id.* at 9.

a similar analysis. He then reviewed the scientific literature in this case, including the case-control studies, cohort studies, and meta-analyses, before providing a summary for the human data.[181] As to the human evidence, Dr. Jameson concluded that there is "limited" evidence, as defined by IARC, for the carcinogenicity of glyphosate.[182]

Next, Dr. Jameson conducted a hazard assessment of the experimental animal data for glyphosate formulations, reviewing cancer bioassays in mice and in rats.[183] In summary, he concludes that there is "sufficient" evidence that glyphosate causes different types of tumors in experimental animals.[184] Lastly, Dr. Jameson performed a hazard assessment of the mechanistic data for glyphosate, concluding there is strong evidence indicating that glyphosate is genotoxic and induces oxidative stress.[185] Overall, Dr. Jameson concludes "to a reasonable degree of scientific certainty that glyphosate and glyphosate-based formulations are probable human carcinogens."[186] Further, he concludes "to a reasonable degree of scientific certainty that glyphosate and glyphosate-based formulations cause NHL in humans."[187] Dr. Jameson explained that although he relied upon the IARC Monograph, he provides

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[181] *See* Dr. Jameson Report at 12-19.
[182] *Id.* at 19.
[183] *Id.* at 19-27.
[184] *Id.* at 29.
[185] *See id.* at 30-31.
[186] Dr. Jameson Report at 31-32.
[187] *Id.* at 32.

his own opinion that is not the IARC's opinion.[188] Dr. Jameson draws from the IARC Monograph to reach his conclusion that glyphosate and GBHs cause NHL in humans.[189]

Monsanto takes issue with Dr. Jameson's opinions, focusing on his concession that animal bioassay studies are used to determine if the chemical can cause cancer in animals, not humans.[190] Although animal bioassay studies focus on animals, "[o]ther forms of evidence including toxicology, *in vivo* studies, *in vitro* studies, animal studies, and case studies can be used together to show causation."[191] Although animal toxicology studies alone may be insufficient to establish general causation, Dr. Jameson's opinions about the animal toxicology studies are relevant to the issue of general causation. Dr. Jameson's opinions and conclusions in his expert report meet the reliability requirement under *Daubert.* These opinions are reliable because he utilized sound scientific methodologies in reaching his conclusions and are therefore admissible.

E. Dr. Neugut

Dr. Neugut, M.D., Ph.D. is a practicing medical oncologist, a Professor of Cancer Research and Professor of Medicine and Epidemiology at Columbia

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[188] *Daubert* Hearing Tr. 417:20-418:13.
[189] *Id.* 418:22-419:4.
[190] Def.'s Opening Br. at 22.
[191] *Tumlinson I*, 2013 WL 7084888, at *9.

University, and Associate Director for Population Sciences for the Herbert Irving Comprehensive Cancer Center.[192] His specialty is epidemiology. Dr. Neugut reviewed the relevant literature, and concluded that "epidemiologic and scientific evidence currently available leads to the conclusion to a reasonable degree of scientific certainty for most expert, objective, and reasonable viewers, myself included, that the use of glyphosate in its various combinations can cause non-Hodgkin lymphoma."[193] As to the epidemiology evidence, there is no dispute that Dr. Neugut is qualified to render these opinions.[194] The issue is whether his opinions satisfy the reliability prong of the *Daubert* standard.

Dr. Neugut's report reviewed various epidemiology studies that were broken up by cohort studies, case-control studies, and meta-analyses and discussed their results.[195] The report next reviewed toxicity studies, looking at animal studies and studies in human cells *in vitro*.[196] After this review, Dr. Neugut analyzed the Bradford Hill criteria for causation and addressed each factor and whether the factors weigh in favor that the association of glyphosate exposure and NHL is causal.[197]

The MDL Court explained there were significant inconsistencies between the

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[192] Pls.' Ex. 6, Expert Report of Dr. Alfred I. Neugut, MD, PhD in Support of General Causation on Behalf of Plaintiffs at 2 [hereinafter Dr. Neugut Report].
[193] *Id.* at 23.
[194] *See* Def.'s Opening Br. Monsanto argues that Dr. Neugut is not qualified to render opinions on rodent bioassay data or mechanistic data. *See id.* at 22, n.42 and 42, n.71.
[195] Dr. Neugut Report at 11-17.
[196] *Id.* at 17-20.
[197] *Id.* at 20-22.

testimony he offered at his deposition and at the *Daubert* hearing.[198] According to the MDL Court, the problems with Dr. Neugut's testimony "were far more apparent in the courtroom" than how they are reflected in the written transcript.[199] Although Dr. Neugut is qualified to testify about the epidemiology evidence, his misstatements during his testimony cast into doubt the reliability of his opinions. Similar to the MDL Court, this Court finds that given the inconsistencies in Dr. Neugut's testimony, his opinions do not satisfy the *Daubert* standard for reliability.[200] Plaintiffs failed to demonstrate by a preponderance of the evidence that Dr. Neugut's opinions are reliable. Therefore, Dr. Neugut's opinions are inadmissible under D.R.E. 702 and *Daubert*.

F. Dr. Nabhan

Dr. Nabhan is a hematologist and medical oncologist "with a specialty in the diagnosis and management of patients with all types of lymphoma, including non-Hodgkin (NHL)."[201] During the *Daubert* hearing, Dr. Nabhan reiterated that he was not an epidemiologist.[202] He is a clinician, who has incorporated epidemiology and

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[198] *See In re Roundup Litig.*, 2018 WL 3368534, at *30 ("However, Dr. Neugut's testimony at the *Daubert* hearing was of a much lower quality.").
[199] *Id.* (identifying problems with Dr. Neugut's testimony).
[200] *See id.* at *30-31 (identifying a few examples of the problems with Dr. Neugut's testimony that undermined its reliability).
[201] Pls.' Ex. 8, Expert Report of Dr. Nabhan in Support of General Causation on Behalf of Plaintiffs at 1 [hereinafter Dr. Nabhan Report].
[202] *Daubert* Hearing Tr. at 805:1-4, 818:24-819:3.

toxicology into his work and studies.[203] Dr. Nabhan testified that he relied heavily on the IARC in formulating his opinion.[204]

His report looked at mechanistic and animal studies of glyphosate, finding that based on animal data there is "carcinogenic potential for glyphosate."[205] Dr. Nabhan assessed epidemiological studies to examine the carcinogenic risk of glyphosate in humans.[206] Next, he considered meta-analyses on the associations between glyphosate and NHL.[207] He also examined systematic reviews, including the IARC Monograph.[208] Lastly, Dr. Nabhan conducted an analysis of the Bradford-Hill criteria.[209] He concludes that the "weight of the scientific evidence supports causality between Roundup/glyphosate exposure and NHL."[210]

It is not necessary to require a medical doctor to be an epidemiologist in order to testify about epidemiological studies,[211] and this Court agrees that Dr. Nabhan does not have to be an epidemiologist to render his opinion about epidemiological studies. The problem with Dr. Nabhan's opinion is that he relies heavily and

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[203] Dr. Nabhan Report at 3-4.
[204] *Daubert* Hearing Tr. at 844:16-18.
[205] Dr. Nabhan Report at 8.
[206] *Id.* at 11-15.
[207] *Id.* at 15-16.
[208] *Id.* at 16-18.
[209] *Id.* at 19-21.
[210] Dr. Nabhan Report at 22.
[211] *See In re Roundup Litig.*, 2018 WL 3368534, at *33; *In re Mirena IUD Products Liability Litigation*, 169 F. Supp. 3d 396, 426 (S.D.N.Y. 2016) ("Moreover, medical doctors do not need to be epidemiologists in order to testify regarding epidemiological studies.").

uncritically on IARC's conclusions. At the *Daubert* hearing, Dr. Nabhan demonstrated a strong reliance on IARC and its conclusions regarding glyphosate exposure and NHL.[212] The IARC alone does not suffice. Unlike other experts, Dr. Nabhan has not employed appropriate methodologies to reach reliable conclusions regarding that glyphosate can cause NHL for purposes of general causation.[213] The Court finds that Plaintiffs fail to establish the reliability of Dr. Nabhan's opinions under *Daubert*; thus, Dr. Nabhan's opinions are inadmissible under D.R.E. 702.

In sum, Plaintiffs have met their burden by a preponderance of the evidence that the expert opinions of Drs. Ritz, Weisenburger, Portier, and Jameson are admissible. Plaintiffs' have failed to meet their burden as to Drs. Neugut and Nabhan. Therefore, Defendant Monsanto Company's *Daubert* Motion is **GRANTED**, in part, and **DENIED**, in part, as outlined.

V. MONSANTO'S MOTION FOR SUMMARY JUDGMENT

A. Motion for Summary Judgment Standard

Delaware Superior Court Civil Rule 56 mandates the granting of summary judgment where the moving party demonstrates that "there is no genuine issues as to any material fact and that the moving party is entitled to judgment as a matter of

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[212] *See In re Roundup Litig.*, 2018 WL 3368534, at *33-34; *Daubert* Hearing Tr. at 850:7-21 (discussing that the IARC report is "very convincing").

[213] *See In re Roundup Litig.*, 2018 WL 3368534, at *32-33 (holding that Monsanto's motion to exclude Dr. Nabhan's testimony was granted because he did not provide "a reliable basis for concluding that glyphosate can cause NHL as a general matter").

law."[214] If the moving party satisfies its initial burden, the non-moving party must sufficiently establish the "existence of one or more genuine issues of material fact."[215] Summary judgment will not be granted if there is a material fact in dispute or if "it seems desirable to inquire thoroughly into [the facts] in order to clarify the application of the law to the circumstances."[216] "All facts and reasonable inferences must be considered in a light most favorable to the non-moving party."[217]

B. Monsanto's Motion for Summary Judgment Analysis

Monsanto argues that it is entitled to summary judgment because Plaintiffs failed to present admissible expert testimony under *Daubert* to prove general causation.

Toxic tort cases, such as here, require the plaintiffs to prove general causation. This must be satisfied by presenting expert testimony because the issue of general causation is outside the knowledge of lay jurors. If plaintiffs do not provide proof of general causation, then they are unable to establish an essential element of their case and summary judgment should be granted in favor of the defendant. Because Plaintiffs have provided expert opinions that are admissible under *Daubert* to prove

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[214] Super. Ct. Civ. R. 56(c).
[215] *Quality Elec. Co., Inc. v. E. States Const. Serv., Inc.*, 663 A.2d 488, 1995 WL 379125, at *3-4 (Del. 1995). *See also* Rule 56(e); *Moore v. Sizemore*, 405 A.2d 679, 681 (Del. 1979).
[216] *Ebersole v. Lowengrub*, 180 A.2d 467, 469-70 (Del. 1962).
[217] *Nutt v. A.C. & S. Co., Inc.*, 517 A.2d 690, 692 (Del. Super. 1986) (citing *Mechell v. Palmer*, 343 A.2d 620, 621 (Del. 1975); *Allstate Auto Leasing Co. v. Caldwell*, 394 A.2d 748, 752 (Del. Super. 1978)).

general causation, Monsanto is not entitled to summary judgment.

VI. PLAINTIFF'S *DAUBERT* MOTION TO STRIKE

Plaintiffs also seek to exclude certain opinions of four of Monsanto's experts, including Drs. Goodman, Foster, Rider, and Mucci. They argue that these experts' opinions fail to meet the *Daubert* standard because they are based on unsound methodologies and are unreliable.

A. Dr. Goodman

Dr. Goodman is a Professor in the Department of Pharmacology and Toxicology at Michigan State University and is board certified in toxicology.[218] Dr. Goodman reviewed scientific literature regarding glyphosate and its potential genotoxicity, and concluded that GBFs, glyphosate and AMPA "should be regarded as non-genotoxic materials."[219]

Plaintiffs contend that Dr. Goodman's opinions are inadmissible because he discounted two human *in vivo* studies and his opinions are based on results-driven methodology.[220] Similar arguments were raised in the MDL case and that Court found that his method and analysis were not so flawed as to require exclusion, and therefore his opinions were admissible.[221]

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[218] Pls.' Ex. 82, Glyphosate: Review and Interpretation of Key Aspects of the Scientific Literature Concerning Genotoxicity and Oxidative Stress Data by Jay I. Goodman at 1 [hereinafter Dr. Goodman Report].
[219] *Id.* at 3.
[220] Pls.' Answering Br. at 63-70.
[221] *See In re Roundup Litig.*, 2018 WL 3368534, at *34.

This Court agrees with the well-reasoned finding of the MDL Court.[222] The methodology utilized by Dr. Goodman meets the *Daubert* reliability requirement because it has been tested, published, peer-reviewed, and is generally accepted in the scientific community.[223] Monsanto has met its burden that Dr. Goodman's testimony is admissible.

B. Dr. Foster

Dr. Foster is a toxicologist who engages in research and conducts animal studies in the field.[224] He concluded, upon review of animal studies, that "within a reasonable degree of scientific certainty, glyphosate is not a rodent carcinogen."[225] Dr. Foster is qualified to offer his opinions based on his experience and training in toxicology. Plaintiffs seek to exclude his opinions arguing that they are not based on sound methodology.[226] Plaintiffs raise issues with Dr. Foster's method of comparing what are known as the Lankas study and the Atkinson and Suresh studies.[227]

Similar to Plaintiffs experts, Dr. Foster reviewed the relevant literature and

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[222] *See In re Roundup Litig.*, 2018 WL 3368534, at *34 ("Although he reaches different conclusions about what the weight of the mechanistic evidence shows, his analysis is not so flawed or one-sided that his opinions need be excluded.").
[223] *See Tumlinson I*, 2013 WL 7084888, at *2 (citing *Daubert I*, 509 U.S. at 593-94).
[224] Pls.' Ex. 65, Expert Witness Report of Warren G. Foster, Ph.D. FCAHS at 3 [hereinafter Dr. Foster Report].
[225] *Id.* at 29.
[226] Pls.' Answering Br. at 70-74.
[227] *See id.* at 70-72. Plaintiffs also raise concern that the Atkinson and Suresh studies do not examine all of the treated animals. *Id.* at 72.

evaluated the various studies. Although Dr. Foster had a different interpretation of the same studies relied upon by Plaintiffs, this does not render his opinions inadmissible.[228] Dr. Foster's opinions are scientifically reliable because his methodology is rooted in science.[229] Monsanto has demonstrated that Dr. Foster's opinions are reliable under *Daubert*, and therefore are admissible under D.R.E. 702.

C. Drs. Rider and Mucci

As to Drs. Rider and Mucci, Plaintiffs requested at oral argument that if they are going to testify at trial that their testimony be limited to epidemiology. Plaintiffs move to strike both of these doctors' opinions because they did not use reliable methodology.[230] Both experts reviewed the relevant epidemiology studies, like the other experts, and reached their own conclusions. Dr. Rider concluded that "the epidemiologic evidence does not provide a basis sufficient to opine that glyphosate-based herbicides are causally related to NHL."[231] Dr. Mucci opines "to a reasonable degree of scientific certainty, that the epidemiological evidence does not provide a scientific basis to support a causal relationship between exposure to glyphosate-based herbicides and the risk of NHL."[232]

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[228] *See In re Asbestos Litig.*, 911 A.2d at 1201 ("When a trial court determines that an expert's testimony is reliable, this does not mean that contradictory expert testimony by default is unreliable.").
[229] *See Bowen*, 906 A.2d at 794 (citing *Daubert I*, 509 U.S. at 590).
[230] Pls.' Answering Br. at 74.
[231] Pls.' Ex. 93, Expert Report of Jennifer R. Rider, ScD at 47 [hereinafter Dr. Rider Report].
[232] Pls.' Ex. 94, Expert Report of Lorelei A. Mucci, ScD, MPH at 71 [hereinafter Dr. Mucci Report].

Drs. Rider and Mucci provide opinions on epidemiology, and they utilized reliable methods to reach their conclusions about the epidemiology evidence. Drs. Rider and Mucci used sufficiently reliable methods under *Daubert* to reach their respective conclusions on the epidemiological evidence, and their opinions will be limited to that evidence.

Monsanto has established the admissibility of their experts' opinions by a preponderance of the evidence. Therefore, Plaintiff's *Daubert* Motion to Strike Certain Opinions of Defendant's Expert Witnesses is **DENIED**.

VII. CONCLUSION

For the reasons stated above, Monsanto's *Daubert* Motion is **GRANTED**, in part, and **DENIED**, in part, and its Motion for Summary Judgment is **DENIED**. Plaintiffs' *Daubert* Motion to Strike Certain Opinions of Defendant's Expert Witnesses is **DENIED**.

IT IS SO ORDERED.

Judge Vivian L. Medinilla

oc: Prothonotary

cc: All Counsel on Record (via e-filing)