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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 3:16-md-02741-VC
This document relates to: ALL ACTIONS	

MONSANTO COMPANY'S SUPPLEMENTAL *DAUBERT* MEMORANDUM REGARDING DR. DENNIS WEISENBURGER'S TESTIMONY REGARDING EPIDEMIOLOGY EVIDENCE

INTRODUCTION

In accordance with the Court's request for further briefing, *see* Pretrial Order No. 44, ECF No. 1537, Monsanto Company ("Monsanto") submits this supplemental memorandum regarding Dr. Dennis Weisenburger's testimony regarding epidemiology evidence. Like plaintiffs' other experts, Dr. Weisenburger has changed his opinions in outcome-oriented ways to try to support plaintiffs' general causation arguments. In particular, Dr. Weisenburger's egregious, misleading approach to the latency issue (the period between exposure to glyphosate and the development of non-Hodgkin's lymphoma ("NHL")) and two other important methodologic flaws discussed below show that his general causation opinion fails to satisfy the "exacting standards of reliability," *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000), required for expert opinions to survive *Daubert* scrutiny.

ARGUMENT

First, before the *Daubert* hearing, Dr. Weisenburger submitted written comments to the United States Environmental Protection Agency ("EPA") regarding the EPA Office of Pesticide Program's September 2016 glyphosate issue paper.[1] In those written comments, Dr. Weisenburger argued that the EPA had misinterpreted his 1992 paper on NHL latency when the EPA concluded that the De Roos (2005) cohort study had sufficient follow up to provide reliable evidence of a lack of an association between glyphosate-based herbicides ("GBHs") and NHL.[2] In his written comments, Dr. Weisenburger argued for a longer latency period:

> [L]ong-term, low-level exposure would be expected to result in a long latency period. . . . Since exposure to glyphosate would be expected to be long-term, low-level exposure, the citation of my [1992] paper for the proposition that a latency period for glyphosate exposure in relation to NHL can range from 1-25 years would contradict the conclusion of my 1992 paper. ***I would expect the average latency period for glyphosate exposure in relation to potential NHL to be at the upper end of this range, most likely 20 or more years from initial exposure.***

[1] *See* Letter from Dr. Weisenburger to Steven Knott, EPA ("Weisenburger EPA Comments") (attached as Ex. 1) (https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0412).

[2] *Compare id*. (citing page 67 of September 2016 EPA Office of Pesticide Program's September 2016 glyphosate issue paper) *with* EPA Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 67-68 (Sept. 12, 2016) (excerpts attached as Exhibit 2) (https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094).

Weisenburger EPA Comments (emphasis added).

However, by the time of the *Daubert* hearing, Dr. Weisenburger apparently realized (or had had been coached) that this latency opinion would hurt plaintiffs' general causation arguments, so he modified his opinion in an effort to bolster plaintiffs' litigation position. For example, in response to Judge Petrou's question – "Can you tell us what is known about the latency period for NHL?" – Dr. Weisenburger failed to disclose the unequivocal latency opinion that he had submitted to the EPA and gave the following testimony instead:

> ***So we don't really know for glyphosate what the latency period is***. We do know from the Eriksson study that you had to be exposed – you had to have – you had to follow the patients for at least 10 years after their exposure to begin to see cases. But that's about all we know about glyphosate.

Amended Tr. of Proc. at 173-74 (Mar. 5, 2018) (emphasis added). The next day, Judge Petrou revisited the latency issue with Dr. Weisenburger: "So I was curious as to NHL whether there is a generally accepted medical understanding of the latency period, or whether this remains kind of a question mark at this point." Tr. of Proc. at 245-46 (Mar. 6, 2018). Again, Dr. Weisenburger failed to disclose the unequivocal opinion he had submitted to the EPA:

> Well, it is a question mark, because latency depends on a lot of things. It depends on the potency of the chemical. If it's a strong carcinogen, the latency would be short, and it would induce cancers early. If the carcinogen was a weak carcinogen it – it might take many, many years.

Id. at 246.

As the Court is aware, the latency issue is centrally important to any evaluation of plaintiffs' experts' reliance on the early case-control studies in North America, which involved cases diagnosed with NHL in the late 1970s to mid-1980s, ten years or less after the introduction of GBHs on the market. *See id*. at 280-85 (questions by Court and testimony by Dr. Weisenburger regarding latency issues). Dr. Weisenburger's reliance on these case-control studies in the face of his own unequivocal opinion previously submitted to the EPA (but not disclosed by him in this litigation) of an average glyphosate-NHL latency period of 20 or more years shows that he used an unreliable methodology. Dr. Weisenburger's reliance on these case-control studies is especially

problematic, given his admissions: (a) that 70% or more of all NHL cases are idiopathic (cause unknown); and (b) that a rising wave of NHL was detected in the United States starting in the 1950s that was not caused by glyphosate because glyphosate was not on the market at that time. *Id*. at 249.

To be sure, Dr. Weisenburger tried to play the latency issue both ways during the hearing. When testifying about the 2018 Journal of National Cancer Institute cohort study by Andreotti, *et al*. ("2018 NCI study") (Plaintiffs' *Daubert* Hrg. Ex. 12), he argued for a ***longer*** latency period than the period he had provided in his comments to the EPA. The 2018 NCI study included significantly longer follow-up even than the De Roos (2005) cohort study, with follow-up times spanning more than 30 years from exposure to NHL diagnosis. *See* Tr. of Proc. at 386 (Mar. 7, 2018); Tr. of Proc. at 860-61 (Mar. 9, 2018). Feigning an inability to opine to a specific latency period, Dr. Weisenburger suddenly argued that even 30 years of follow up would not be enough:

> [I]n these cohort studies, one usually expects to follow these patients for not just 18 years, but usually for 30 to 40 years, or even up to the time when most of the people have died, so you have a complete story of what happened, because if the median latency period is long, if it's 30 years or 35 years, you wouldn't see enough of the disease at this kind of follow-up to really give you elevated risks.

Amended Tr. of Proc. at 188 (Mar. 5, 2018).

In sum, despite having previously opined in a submission to EPA to an average glyphosate-NHL latency period of 20 years or more, at the *Daubert* hearing, Dr. Weisenburger opined both that the North American case-control studies were reliable notwithstanding a maximum possible latency period for cases of roughly 10 years and that the 2018 NCI study was not reliable because it "only" allowed for a latency period of 30 or 35 years. Of course, the issue for this Court at this time is not determining the scientifically correct answer regarding latency; the issue is whether Dr. Weisenburger's general causation opinions are based on a scientifically reliable, consistently applied methodology. They clearly are not. Instead, Dr. Weisenburger used a litigation-influenced, results-driven methodology that led him to present inconsistent, "moving target" opinions in an obvious effort to bolster plaintiffs' general causation arguments. But that is

contrary to well-established *Daubert* principles. For example, in multidistrict litigation proceedings, a district court excluded a plaintiffs' expert's general causation opinions because the expert's analysis was "results driven"; his "methodology and selection of relevant evidence changed based on the results they produced"; and he "ignored his own analyses and methods that produced contrary results." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 145 F. Supp. 3d 573, 594 (D.S.C. 2015), *amended on reconsideration*, 2016 WL 827067 (D.S.C. Feb. 29, 2016). That exclusion ruling recently was affirmed on appeal. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, --- F.3d ---, 2018 WL 2927629, at *5 (4th Cir. June 12, 2018) (stating that "[r]esult-driven analysis, or cherry-picking, undermines principles of the scientific method"). Likewise, other courts repeatedly have excluded experts who engaged in "situational science" or presented "moving target" opinions.[3]

Second, Dr. Weisenburger's concession at the *Daubert* hearing regarding the data reported in the Eriksson (2008) case-control study (Plaintiffs' *Daubert* Hrg. Ex. 17) provides further support for the conclusion that his general causation opinion is not based on a scientifically reliable methodology. In response to the Court's questions, Dr. Weisenburger conceded that it would be "a lot more reliable" to use the multivariate analysis than the univariate analysis in Eriksson (2008). Tr. of Proc. at 237 (Mar. 6, 2018). By contrast, in his expert report, he relied on the univariate analysis to support his general causation opinion and stated that the univariate analysis showed a "statistically-significant increase[] in the risk of NHL." Weisenburger Expert Report at 4

[3] *See, e.g., In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, MDL No. 2342, 2015 WL 7776911, at *10-11 (E.D. Pa. Dec. 2, 2015) (excluding general causation opinions of expert who engaged in "situational science" by "plac[ing] importance upon statistical principles when they support his opinion, and ignor[ing] them when they do not"), *aff'd*, 858 F.3d 787 (3d Cir. 2017); *Ed Peters Jewelry Co. v. C&J Jewelry Co.*, 124 F.3d 252, 260 (1st Cir. 1997) (affirming exclusion of expert; stating that "the 'moving target' nature of the valuation alone provided ample reason for the district court to scrutinize [the expert's] methodology with special skepticism"); *Haller v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1271, 1296-97 (M.D. Fla. 2009) (excluding expert whose "veritable moving target" opinion "smacks of post-hoc-rationalization and is devoid of the intellectual rigor that *Daubert* demands"); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 536-37 (W.D. Pa. 2003) (excluding causation opinions of experts who presented inconsistent, "moving target" opinions; stating that "[s]uch inherent inconsistency itself renders plaintiff's experts' methodology unreliable"); *Glastetter v. Novartis Pharm. Corp.*, 107 F. Supp. 2d 1015, 1032 (E.D. Mo. 2000) (excluding causation opinion of expert; stating that his "opinion on whether bromocriptine is a vasoconstrictor is a moving target"), *aff'd*, 252 F.3d 986 (8th Cir. 2001).

(Plaintiffs' *Daubert* Hrg. Ex. 4). However, the multivariate analysis resulted in an odds ratio that is not statistically significant. *See* Eriksson (2008) at page 1661 (Table VII).

Third, Dr. Weisenburger completely failed to discuss the publicly available NAPP data in his expert report, which further undermines any contention by plaintiffs that his general causation opinion is based on a scientifically reliable methodology. As Dr. Weisenburger admitted at the hearing, when the data from the De Roos (2003) and McDuffie (2001) case-control studies were pooled and adjusted for other pesticides, the result was not statistically significant. Tr. of Proc. at 254 (Mar. 6, 2018). He also conceded: (a) that certain other pesticides (2,4-D; dicamba; malathion) are associated with NHL in case-control studies; (b) that adjusting for exposure to those pesticides "is absolutely appropriate, and a good idea, and it improves the numbers"; and (c) that exposure to other pesticides "can be a major confounder for whether glyphosate can cause [NHL]." *Id*. at 254-55. In light of those concessions, it was not scientifically reliable for Dr. Weisenburger to ignore the NAPP data – and was particularly improper, given his role as an NAPP co-author – when analyzing the general causation question at issue here.

CONCLUSION

For the reasons set forth above and in Monsanto's prior written and oral arguments, the Court should exclude Dr. Weisenburger's opinions.

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Respectfully submitted,

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