UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITGATION	MDL No. 2741 Case No. 16-md-02741-VC
This document relates to: *Hardeman v. Monsanto Co.*, 16-cv-0525-VC	**PRETRIAL ORDER NO. 159: DENYING MONSANTO'S MOTIONS FOR JUDGMENT AS A MATTER OF LAW OR, IN THE ALTERNATIVE, FOR A NEW TRIAL ON NON-DAMAGES GROUNDS**

This ruling addresses Monsanto's post-trial motions other than those related to damages. The Court will file a separate ruling relating to damages on Monday.

1. There was no material difference between the quality of the causation evidence presented pretrial and at trial. If anything, the testimony of the plaintiffs' causation experts at trial was more reliable than their testimony during the *Daubert* hearings, because the Court barred them from offering certain portions of their opinions at trial that were without any scientific basis. Thus, for the reasons expressed in Pretrial Orders Nos. 45 and 85, Mr. Hardeman presented sufficient admissible evidence of causation. *See* Dkt. Nos. 1596, 2799. One note relating to the trial testimony: although Monsanto is correct that Dr. Weisenburger's estimates of Mr. Hardeman's exposure levels were higher than could be supported by Mr. Hardeman's own testimony, the difference is merely a matter of degree. Mr. Hardeman's exposure levels still far exceeded the threshold used in most of the epidemiological literature, and specifically the McDuffie and

Eriksson studies.

2. For the reasons expressed in Pretrial Order No. 101 and at the hearing on July 2, 2019, Mr. Hardeman's claims are neither expressly nor impliedly preempted under current Supreme Court caselaw. *See* Dkt. No. 2937, 4453; *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005).

3. Although the most strenuous objections to the causation instruction came from the plaintiff, Monsanto now seeks relief based on it. The instruction, which included a modification to CACI 430, was not error, largely for the reasons stated on the record during trial. With respect to the discrete points Monsanto now raises in its motion, it bears noting that nowhere does the causation instruction refer to hepatitis C. Monsanto objects that the modification discouraged the jury from "considering other causes or the possibility of an unknown cause," but the instruction refers generically to "other factors" that might cause non-Hodgkin's lymphoma. If the jury focused on hepatitis C, that is a product not of the instruction, but of the evidence presented at trial. Nor did the modification shift the burden of proof to Monsanto; it asked the jury to consider whether Mr. Hardeman had or had not proven that his exposure to Roundup was sufficient to cause his NHL.

4. For the reasons expressed in Pretrial Order No. 101 and at the hearing on July 2, 2019, there was no error in either the negligent or strict liability failure-to-warn instructions. *See* Dkt. Nos. 2937, 4453. Nor was it error to list the amount of stipulated damages in the verdict form.

5. Monsanto is not entitled to a new trial based on the excusal of Juror #4. To begin, Monsanto waived this argument by failing to object at trial. Defense counsel requested that the Court conduct a further investigation before excusing her, but did not object on the record, and in fact stated that Monsanto would "defer to" the Court. In any event, it was appropriate to excuse Juror #4 after three separate jurors confirmed her statement – made after the second day of trial –

that she already knew how she was going to vote, and nothing would change her mind. *See Harrell v. Taylor*, No. C 00-2516 PJH (PR), 2008 WL 4344582, at *15 (N.D. Cal. Sept. 22, 2008) (describing the trial court's discretion surrounding investigations of juror misconduct). And as explained at the July 2, 2019, hearing, the Court's telephone conversation with Juror #4 after her excusal effectively confirmed her conduct.

6. Under California law, a design defect claim has an amoeba-like quality that makes it near impossible to define with any degree of precision. *See Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 427 (1978) ("[T]he term defect as utilized in the strict liability context is neither self-defining nor susceptible to a single definition applicable in all contexts."). Mr. Hardeman's lawyers did not do much to help clarify this ambiguity. Their theory shifted from hearing to hearing (sometimes within the same hearing), and it was difficult to pin them down on the contours of the design defect claim.

Taking that as a backdrop, there could be two possible bases for the jury's design defect verdict. One is that Roundup was defective because it was sold without a warning. That theory largely, if not entirely, overlaps with the failure-to-warn claim, but that isn't necessarily a problem. It appears that California law allows design defect claims of this nature, although the law, as mentioned, is far from clear. *Cf. Arena v. Owens-Corning Fiberglas Corp.*, 63 Cal. App. 4th 1178, 1186 (1998) (explaining that the term design defect "relates more to a legal conclusion that a product has deviated in some manner from what is reasonably expected, than it does to a description of a specific mechanical shortcoming or flaw"). And even if one or the other claim is extraneous in this context, they will simply rise and fall together.[1]

[1] Perhaps there is a slight amount of daylight between the two where a jury concludes that the risk of a product was not known or knowable, as is necessary for a plaintiff to prevail on either a negligent or strict liability failure-to-warn claim, but that didn't happen here.

The second basis – which is the theory Mr. Hardeman's lawyers ultimately told the Court they intended to pursue – is that, warning or no warning, Roundup is so dangerous that it should not be on the market at all, at least for purchase by residential users. It appears that California law also allows design defect claims of this nature. *See Arnold v. Dow Chem. Co.*, 91 Cal. App. 4th 698, 716 (2001) ("Appellants' claim is that, due to the content and properties of the products, they cannot safely be used in the home. Period.").[2]

Based on the evidence presented at trial and on closing argument by Mr. Hardeman's counsel, the jury verdict must be understood to reflect the first theory: Roundup is defective when sold without a warning. In other words, the defect was the absence of a warning, which effectively caused the design defect claim to merge into the failure-to-warn claim. Perhaps Monsanto's counsel put it best in closing argument: "The first is design defect, and what they are saying is that an ordinary consumer who used Roundup like Mr. Hardeman did would not have thought there was cancer associated with it so there should have been a warning." *See* Dkt. No. 3237 at 2749. Construed that way, there is no reason to overturn the jury's verdict on the design defect claim. There was sufficient evidence to support a finding that Roundup is "defective" within the meaning of California law when sold without a warning.

But to the extent Mr. Hardeman believes that he won a jury verdict on the design defect theory he offered to the Court during discussion of jury instructions (namely, that Roundup should

[2] Both theories are based on the consumer expectations test, "which asks whether the product performed as safely as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner." *Saller v. Crown Cork & Seal Co.*, 187 Cal. App. 4th 1220, 1232 (2010). Because an ordinary consumer could form an expectation about the general safety of a residential lawncare product, it was appropriate for Mr. Hardeman to proceed under this test. *See Arnold*, 91 Cal. App. 4th at 727 (holding that a design defect claim against a pesticide was properly understood as a consumer expectations claim).

not have been sold for residential use regardless of whether there was a warning), it's worth clarifying that he did not. Mr. Hardeman presented no evidence that Roundup is inherently defective regardless of whether accompanied by a warning. He presented no expert testimony that Roundup could not be used safely with the proper precautions. And he made no argument to the jury that Roundup simply shouldn't be on the shelves for residential use. Indeed, no colorable argument could be made in this regard, at least based on the evidence at trial and the evidence the Court has reviewed in this case over the past several years.

In sum, the evidence showed no greater defect than the absence of a warning. If this Court were incorrect in interpreting California law as permitting a design defect claim based on the absence of a warning, and if thus Mr. Hardeman's only true path to victory on the design defect claim were the theory that Roundup should not have been sold for residential use at all, then judgment as a matter of law would be entered for Monsanto on the design defect claim.[3]

7. Monsanto argues that the jury was presented an inaccurate view of the scientific and regulatory landscape based on the Court's "selective admission" of evidence regarding global regulatory approvals. This argument is fundamentally about the scope of the trial. While Monsanto is correct that the jury wasn't presented with the entire regulatory landscape, that is primarily a function of the evidentiary parameters Monsanto itself requested, and was largely granted, in response to motions in limine. Of course, determining which evidence to admit – and for what

[3] Nor was there sufficient evidence for a jury to conclude that Roundup is defective because of the formulation of the product. Mr. Hardeman did not prove that Roundup is defective while glyphosate alone is not (or while some other glyphosate formulation is not). But that does not defeat Mr. Hardeman's design defect claim, because even assuming glyphosate should be understood as a raw material (which is doubtful), a product made from a raw material may still suffer from a design defect. *See Arena*, 63 Cal. App. 4th at 1191 (holding that "raw asbestos is a product that may have a design defect when it fails to meet the commonly accepted minimum safety assumptions of its ordinary consumers") (internal quotations omitted).

purpose – required a certain amount of line-drawing. But Monsanto is objecting that it was denied a free hand to draw its own evidentiary boundaries, without any corresponding change in the boundaries set for Mr. Hardeman.

Before trial, Monsanto moved to exclude evidence of its conduct after the summer of 2012. Because Mr. Hardeman stopped using Roundup at that time, Monsanto argued that its conduct past that date was irrelevant to its liability for his harm.[4] In particular, Monsanto wanted to avoid introduction of evidence about its aggressive attempt to discredit the 2015 IARC decision to classify glyphosate as a probable carcinogen, as well as evidence of its efforts to influence U.S. regulators in the months leading up to and following the IARC decision. The Court granted this request under Rule 403 to avoid undue risk that the jury would punish Monsanto for conduct that couldn't have harmed Mr. Hardeman.

Monsanto now complains that it was improper to admit the fact of IARC's decision but exclude evidence about why regulators continued to approve glyphosate "after, and often in response to, IARC." That sounds reasonable out of context. But recall that, for the most part, only the fact of the IARC classification was admitted, not the details underlying the classification. Similarly, the fact that regulators continued to approve glyphosate following the IARC classification was admitted, just not the details underlying those decisions. Therefore, the jury was fully aware that the regulators were not swayed by the IARC classification.[5] But it would have been unfair to Mr. Hardeman to allow Monsanto to introduce the details of various regulatory

[4] Post-2012 scientific studies were of course still admissible for purposes of the Phase 1 causation inquiry (namely, whether Roundup caused Mr. Hardeman's NHL).

[5] With respect to Monsanto's argument that it should have been allowed to admit the post-IARC conclusions of additional regulators beyond the EPA and the main European regulators (such as Health Canada), that evidence was properly excluded as cumulative under Rule 403.

decisions without also admitting the details of the competing IARC classification, along with evidence of Monsanto's efforts to discredit IARC and to influence U.S. regulators. To give just one example, before trial the Court excluded evidence of an April 2015 conversation between a Monsanto executive and an EPA official in which the EPA official stated he "should get a medal" if he could "kill" an impending HHS investigation into glyphosate. Because Monsanto continued to contend that this sort of post-2012 evidence should not be admitted under Rule 403, that same principle counseled for exclusion of much of the evidence surrounding the regulatory decisions.

Of course, Monsanto could have chosen to flick the domino that would have brought in much more post-2012 evidence. The Court informed Monsanto that it could bring in the testimony from Dr. Portier about the details underlying the regulators' post-IARC conclusions that it now contends was improperly excluded, but that the details of the IARC classification, the evidence surrounding Monsanto's attacks on IARC, and the attempts to influence U.S. regulators would then also be admissible. *See* Dkt. No. 3236 at 2481. Monsanto declined. This appears to have been good trial strategy on Monsanto's part, considering the recent damages awards against Monsanto in San Francisco and Alameda County state courts, following trials where virtually all this evidence seems to have come in. But in any event, it would have been unfair to allow Monsanto to expand the scope of its case while continuing to bind Mr. Hardeman to the limits that Monsanto fought so hard to put in place pretrial.[6]

[6] Monsanto's objection largely springs from the Court's decision to exclude this evidence from Phase 2, the liability phase of the trial. To the extent Monsanto objects to the exclusion of worldwide regulatory approvals from Phase 1, the causation phase of the trial, that decision had a separate, independent basis. As previously explained, the primary causation inquiry is what the scientific studies show, not what a regulatory body concluded they show. Thus, while regulatory decisions were certainly relevant to the causation phase, they were of more limited probative value than the underlying scientific data. And, notably, Monsanto was permitted to introduce evidence of continuing approval by the EPA, the European Food Safety Authority, and the European Chemicals

8. It was not error to exclude the EPA's 1993 Re-registration Eligibility Determination and 2009 memorandum on Alkyl Amine Polyalkoxylate surfactants. To begin, it is unclear how Monsanto was prejudiced by the exclusion of these exhibits given that it was permitted to elicit testimony about both. Moreover, there is significant extraneous information in both documents, which total over 350 combined pages. The Re-registration Eligibility Determination has discussion of, among other topics, glyphosate's toxicity to freshwater fish and invertebrates, the chemical structure of glyphosate, and the exposure of endangered plant species to glyphosate. The memo on surfactants similarly has extensive discussion of scientific issues that played no role in the case. Perhaps it would have been appropriate, had Monsanto asked, to admit portions of these documents, but the documents as a whole were properly excluded under Rule 403.

9. For the reasons expressed in Pretrial Order No. 104, the Court did not err in excluding Dr. Arber's testimony regarding Mr. Hardeman's BCL6 mutation. *See* Dkt. No. 2942. With respect to Monsanto's argument that Dr. Weisenburger offered an undisclosed opinion regarding hepatitis C and the pathology slides, to the extent that is true (which is questionable), Monsanto was able to adequately respond through Drs. Arber and Levine.

10. For the reasons expressed in Pretrial Order No. 81, the Court did not err in precluding Dr. Levine from offering a general causation opinion that glyphosate does not cause NHL. Monsanto objects that these limits forced Dr. Levine to testify "inaccurately" that she relied solely on Dr. Mucci's general causation opinion. But Dr. Levine in fact testified that it was her opinion – based on her review of the epidemiological literature – that glyphosate was not a cause of non-Hodgkin's lymphoma. She thus made clear that she had an independent basis for excluding

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Agency. *See* Dkt. Nos. 3116, 4037-1. Given the nature of the inquiry for Phase 1, evidence of additional regulatory decisions was properly excluded under Rule 403.

Roundup as a potential risk factor for Hardeman.

During pretrial proceedings, the Court gave Monsanto an opportunity to express how it could be prejudiced by a rule that only the experts who offered opinions during the *Daubert* hearings on general causation may offer general causation opinions at trial. Monsanto offered no persuasive argument that it would be prejudiced, nor could it have done so in light of the many experts it offered up during those hearings (but then declined to call at trial). Again, this appears largely to be a case of Monsanto complaining about a victory it scored pretrial. It was Monsanto that requested the pretrial proceedings be bifurcated between general and specific causation; a natural outgrowth was that if experts were not put to the *Daubert* test in one area, they could not testify at trial in that area.

11. Monsanto identifies a series of statements made by Drs. Ritz and Weisenburger that it contends violated Pretrial Order No. 85. That order instructed the plaintiffs' experts not to "testify that the McDuffie and Eriksson studies stand for the proposition that if someone uses Roundup more than two days per year or more than ten days in their lifetime, their risk of developing NHL doubles." As explained in the order, because those studies did not adjust for the use of other pesticides, a statement to that effect would be unsupported by sound science.

While some of the statements made by the experts came close to the line set by Pretrial Order No. 85, Monsanto is not entitled to relief on this basis. In large part this is a problem of nomenclature. Epidemiologists often use the phrase "doubling of the risk" as a shorthand to describe a study that shows a risk ratio of 2.0. Based on how Dr. Ritz used the term "twofold risk increase" at trial – namely, when discussing the statistical results of specific studies – it was clear in context that she was summarizing the data from the McDuffie and Eriksson studies, rather than testifying to an overall conclusion that someone using Roundup is twice as likely to develop NHL.

Moreover, unadjusted numbers were not categorically inadmissible, and Dr. Ritz repeatedly qualified her testimony by noting that these studies had not adjusted for the use of other pesticides, the significance of which was acknowledged by both sides at trial. *See* Dkt. No. 2930 at 623. In one of the statements flagged by Monsanto, for example, Dr. Ritz notes: "That's where all of the risk is, and it's more than twofold and it's statistically significant but still unadjusted for other pesticides." That is not an inaccurate statement. While Monsanto is correct that such a result does not translate to a general two-fold increase for all Roundup users, it was proper for Mr. Hardeman's experts to relay the results of these studies, so long as they explained that the numbers were unadjusted.

With respect to Dr. Weisenburger's testimony, the Court struck the portion of the testimony to which Monsanto objects, and forced Dr. Weisenburger to take down the chart he was using. A further curative instruction was unnecessary.

12. Finally, it was not error to exclude evidence of Roundup's agricultural benefits. To the extent Monsanto is suggesting that this evidence helps explain why Monsanto chose not to add a warning label to its product, it is unclear why Roundup's efficacy would impact whether consumers should be warned of a risk of developing cancer.

IT IS SO ORDERED.

Date: July 12, 2019

Honorable Vince Chhabria
United States District Court