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9	DEWAYNE JOHNSON	
10	SUPERIOR COURT OF THE STATE OF CALIFORNIA  COUNTY OF SAN FRANCISCO	
11		
13	DEWAYNE JOHNSON,	Case No.: CGC-16-550128
14	Plaintiffs,	PLAINTIFF'S OPPOSITION TO
15	VS.	MONSANTO'S MIL NO. 20 TO EXCLUDE EVIDENCE OF
16	MONSANTO COMPANY,	GHOSTWRITING
17	Defendant.	
18		Trial Judge: TBD
19 20		Trial Date: June 18, 2018 Time: 9:30 a.m. Department: TBD
21		Department: TBD
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23		
24	I. INTRODUCTION  Courts have described ghostwriting as "polluting the scientific literature." Barton v.  Wyeth Pharm., Inc., No. 694 EDA 2010, 2012 WL 112613, at *11 (Pa. Super. Ct. Jan. 3, 2012).  The World Association of Medical Editors has put forth the following statement regarding	
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ghostwriting, "The integrity of the published record of scientific research depends not only on the validity of the science but also on honesty in authorship" <a href="http://www.wame.org/policy-statements">http://www.wame.org/policy-statements</a>.

Judge Karnow has already decided that Monsanto's ghostwriting efforts are relevant to punitive damages and create a triable issue of fact:

The internal correspondence noted by Johnson could support a jury finding that Monsanto has long been aware of the risk that its glyphosate-based herbicides are carcinogenic, and more dangerous than glyphosate in isolation, but has continuously sought to influence the scientific literature to prevent its internal concerns from reaching the public sphere and to bolster its defenses in products liability actions

4/17/2018, Order Re: Sargon 45-46. Judge Karnow specifically cited the very evidence of ghostwriting Monsanto seeks to now exclude:

Ex. 21 (introduced as evidence that Monsanto had a practice of ghostwriting scientific literature about glyphosate in and around 2015), Ex. 22 (introduced as evidence that Monsanto ghost wrote scientific literature about glyphosate as far back as 1999), Ex. 24 (introduced as evidence of Monsanto's sponsorship of literature for the purpose of defending products liability claims regarding glyphosate in 2012), Ex. 25 (introduced to show that Monsanto calculated the benefits of securing certain experts to lend credibility to their sponsored studies in 2012).

*Id.* at Monsanto's own scientists admit that they have ghostwritten papers that were "invaluable assets to regulatory reviews" and for purposes of "product defense." *See infra.* Monsanto's own attorney have acknowledged that articles were ghostwritten. It is therefore shocking for Monsanto to claim their own admissions and actions are false.

In the federal in re: Roundup litigation, Judge Chhabria reviewed the Monsanto documents on ghostwriting and stated:

But the internal e-mails reflect that Monsanto has been ghostwriting reports. And those reports have been portrayed as independent. And you -- I mean, your whole presentation thus far has been about how all the independent science supports a conclusion that glyphosate doesn't cause non-Hodgkin's lymphoma. So, you know, I don't understand how you could have taken the position that the issue of Monsanto drafting reports for allegedly independent experts on whether glyphosate causes non-Hodgkin's lymphoma could be irrelevant to the question of whether there's evidence that glyphosate causes non-Hodgkin's lymphoma. I just don't understand how you could take that position.

Hoke Decl. at Exhibit A, 8/4/2017 In re: Roundup MDL Hearing Tr. 43:4-16. As a result of Judge Chhabria's questioning, Monsanto's own attorneys eventually admitted that Monsanto did ghostwrite articles:

THE COURT: I haven't been tricked by the plaintiffs. I've apparently been tricked by Monsanto when Monsanto internally referred to what it was doing as "ghostwriting." MR. HOLLINGSWORTH: Well, the ghostwriting memos, Your Honor, don't refer to any original science. Okay? What they refer to is review articles done by groups of -- of --

THE COURT: Independent scientists?

MR. HOLLINGSWORTH: -- professors, and independent people, and oftentimes consultants. That goes on. I'll admit that. Okay?

46:15-25.

### II. FACTUAL BACKGROUND

There can be no clearer admission to ghostwriting than the February 19, 2015 email written by Monsanto toxicologist, William Heydens which states:

A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and we ghost-write the Exposure Tox & Genetox sections. ..we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000.

Hoke Decl. at Exhibit B, MONGLY00977265. The Williams article, which Monsanto admits to ghostwriting is titled "Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans" and concludes that "[t]here was no convincing evidence for direct DNA damage;" "Roundup and its components do not pose a risk for the production of heritable/somatic mutations in humans;" and "glyphosate is non carcinogenic;" and "Roundup herbicide does not pose a health risk to humans." In addition to Dr. Heydens

<sup>1</sup> Williams, et al., Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans. Regulatory Toxicology and Pharmacology, 31, 117-165 (2000)

admitting that he ghostwrote the article, Monsanto also documented the writing process for the Williams article.

• WHO: Monsanto Scientists (leads - Heydens, McKee, Wratten) • Mammalian Tox: lead - Heydens

Hoke Decl. at Exhibit C MONGLY02598454, Glyphosate Publications Recommendations for Process. This was not just some harmless act of scientific fraud. In fact, Williams (2000) has been cited in 679 separate journal articles.<sup>2</sup>

The new registration reviews prompted another round of ghostwritten articles. One example, the Kier and Kirkland study<sup>3</sup> was originally written by David Saltmiras of Monsanto. In requesting funding for the manuscript, Saltmiras states that it "will be a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic." Hoke Decl. at Exhibit D, MONGLY02117800, 2/29/2012 manuscript clearance form However, after drafting the manuscript Monsanto felt that "the manuscript turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of credibility among less sophisticated audiences." Hoke Decl. at Exhibit E, MONGLY02145918. Therefore, it was decided that a way to "help enhance credibility is to have an additional author on the papers who is a renowned specialist in the area of genotoxicity ... Dr. David Kirkland was identified as the best candidate." Id. David Saltmiras was therefore taken off of the manuscript as an author and replaced with David Kirkland to give the impression that this study was written by independent experts.

Monsanto has even ghostwritten articles for the specific purpose of supporting their position in litigation involving NHL, Prop 65, and to support its position during the EPA's reregistration. decision for glyphosate. Immediately after IARC deemed glyphosate a carcinogen, Monsanto devised a response plan due to the "[s]evere stigma attached to Group 2A

<sup>&</sup>lt;sup>2</sup> Citation Report from Google Scholar.

https://scholar.google.com/scholar?cites=965770000498629891&as\_sdt=5,47&sciodt=0,47&hl=

<sup>&</sup>lt;sup>3</sup> Kier & Kirkland, "Review of genotoxicity studies of glyphosate and glyphosate-based formulations" Crit Rev Toxicol. 2013 Apr;43(4):283-315

Classification." Hoke Decl. Ex. F, MONGLY01228577. Part of their plan was to convene an expert panel to "[p]ublish comprehensive evaluation of carcinogenic potential by credible scientists." *Id.* Monsanto noted that the "Genetox / MOA" section would be important for "future litigation support." With respect to the expert panel it was noted that from a legal perspective such a panel would be "[a]ppealing; best if use big names; better if sponsored by some group." *Id.* Monsanto proceeded with arranging the expert panel and worked with Intertek, an industry consultancy firm, to create a false impression that the expert panel was independent.

On September 28, 2016, the "independent" expert panel of 12 scientists published its preordained conclusions in the journal Critical Reviews in Toxicology in a paper titled "A review of
the carcinogenic potential of glyphosate by four independent expert panels and comparison to the
IARC assessment." The journal published a special issue dedicated solely to the work of this
expert panel which included an introduction/summary article authored by all of the experts, and
four papers authored by various subgroups of the panel. On October 11, 2016 these articles
were submitted to the EPA to support the re-registration of Roundup® and the continued
exposure of the American public to Roundup®.

In the published article submitted to the EPA, the Conflict of Interest statement declares that, "neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel's manuscripts prior to submission to the journal." These statements are false. Not only did Monsanto regularly contact the authors of the review the manuscripts before they were submitted, they actually wrote parts of the manuscripts. In a January 2016 email to Intertek, for example, William Heydens of Monsanto confirms that he drafted the introduction for the manuscript. Hoke Decl. Ex. G, MONGLY00999487. The independent experts did make edits and contributions to the summary manuscript, however, ultimately it was Heydens who had authority over the content stating "I have gone through the entire document and indicated what I

<sup>4</sup>Williams, et al, A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment, Crit Rev Toxicol. 2016 Sep;46(sup1)

 think should stay, what can go, and in a couple spots I did a little editing." Hoke Decl. Ex. H, MONGLY01000676.

These studies have been replied upon by Monsanto's experts. Hoke Decl. Exhibit I, Foster Rpt. at 46; Exhibit J, Goodman Rpt. at 32-33. They have been relied upon by the EPA, "The CARC evaluated a total of 54 mutagenicity/genotoxicity studies which included studies submitted to the agency, as well as studies reported in the two review articles (Williams et al., 2000, and Kier and Kirkland, 2013" In the final SAP report some panel members also relied on the ghostwritten Williams (2016) stating "consideration of the dataset consisting of responses from 8 rat bioassays (Williams et al., 2016) shows there is no relationship between dose and tumor incidence across rat tumor bioassays." This section of Williams (2016) was simply an edited version of Monsanto's position paper. In Europe, several members of Parliament noted that they were "deeply concerned" EFSA relied on the Kier & Kirkland paper and called for an investigation into whether "Monsanto has deliberately falsified studies on the safety of glyphosate." Hoke Decl. at Exhibit K.

# III. Argument

Evidence is relevant if it has a "tendency in reason to prove or disprove any disputed fact of consequence to the determination of the action..." Cal. Evid. Code § 210 (emphasis added); People v. Nelson (2008) 43 Cal.4th 1242, 1266; Donlen v. Ford Motor Company (2013) 217 Cal.App.4th 138, 148 as modified on denial of reh'g (July 8, 2013). Moreover, section 352 "speaks in terms of undue prejudice. Unless the dangers of undue prejudice, confusion, or time consumption 'substantially outweigh' the probative value of relevant evidence, a section 352 objection should fail." People v. Scott (2011) 52 Cal.4th 452, 490–491 (emphasis in original) (quoting People v. Cudjo (1993) 6 Cal.4th 585, 609); People v. Yu (1983) 143 Cal.App.3d 358, 377 (when applying Section 352, "prejudicial" is not synonymous with "damaging.").

03/documents/december 13-16 2016 final report 03162017.pdf

<sup>&</sup>lt;sup>5</sup> 10/1/2015 GLYPHOSATE: Report of the Cancer Assessment Review Committee, p. 9, file:///D:/Users/jtravers/Downloads/EPA-HQ-OPP-2016-0385-0014.pdf

<sup>6</sup> Final Report of SAP Panel, p. 52. https://www.epa.gov/sites/production/files/2017-

# A. Evidence Of Monsanto's Misconduct Is Relevant And Admissible For Purposes Of Impeachment; To Show Conformity With Monsanto's Business Practice and Intent; and is Directly Relevant to Causation.

Defendants, through their corporate employees, have time and again made the claim that Monsanto is an ethical company that makes a patient's safety its top priority. Evidence of unethical conduct via, *inter alia*, manipulation of publications and other medical literature is relevant and admissible as impeachment evidence to rebut such allegations. Likewise, Monsanto's misconduct is relevant to show its state of mind with respect to the sacrifice of patient safety through the suppression of safety data, and hence is relevant punitive damages.<sup>7</sup>

California Evidence Code Section 1101, states that while evidence of other wrongs or acts is not admissible to prove character or to show action in conformity therewith, it is "relevant to prove some fact (such as motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake or accident..." As such, evidence of Monsanto's unethical conduct in the sponsorship of ghostwritten literature is relevant and admissible to rebut any argument by Defendants that they were acting with reasonable care with respect to its sales and marketing of Roundup® and to show Monsanto's motive and plan regarding its attempts to minimize negative risks and maximize profits. Monsanto's ghostwriting practices are probative evidence of their failure to warn and that Monsanto's inadequate representations about the risk and benefits of Roundup® were not mere inadvertence or mistake, but rather the product of conscious malice. Ghostwriting helps establish Monsanto's state of mind.

Pursuant to Evidence Code 1106 "Any otherwise admissible evidence of habit or custom

<sup>&</sup>lt;sup>7</sup> The Eighth Circuit itself, in discussion of plaintiff's evidence showing conduct worthy of punitive damages called it "ghost-written". *In re Prempro Prods. Liab. Litig. (Scroggin v. Wyeth)*, 586 F.3d 547, 557 (8<sup>th</sup> Cir. 2009), *cert. denied*, 130 S.Ct. 3467 (U.S. 2010). The Nevada Supreme Court, when upholding the jury's punitive damage award in a hormone therapy case, cited to "Wyeth's strategy to undermine scientific studies linking an increased risk of breast cancer to estrogen-progestin hormone therapy included ghostwriting multiple articles" as one of the bases for its ruling. *Wyeth v. Rowatt*, 244 P.3d 765, 784 (Nev. 2010), *cert. denied*, 131 S.Ct. 3028 (June 20, 2011).

 is admissible to prove conduct on a specified occasion in conformity with the habit or custom." The evidence of Monsanto's unethical conduct in the sponsorship of ghostwritten literature including the manipulation of clinical trials and data reported therein is relevant to show that when Monsanto's failed to adequately warn Plaintiff and his prescriber about the risks associated with Actos, it was acting in conformity with its routine practices.

Finally, the entire purpose of Monsanto's ghostwriting was to attempt to tip the scale of scientific literature away from conclusions that glyphosate is carcinogenic and to convince regulators that glyphosate is not carcinogenic. References to Monsanto's ghostwritten articles are rampant throughout the peer-reviewed literature and are cited in articles relied upon by both Plaintiff and Defense experts. Had Monsanto not polluted the scientific literature with unethical behavior, then there would be a greater scientific consensus that glyphosate is carcinogenic and that consensus would have occurred earlier. Earlier knowledge of the carcinogenic properties of glyphosate would also have prevented Mr. Johnson from using RangerPro®.

# B. The Court Should Reject Monsanto's Arguments Regarding Relevance, As Other Courts Have Routinely Done When Facing The Same Issue.

In *In Re Seroquel Products Liability Litigation*, No. 6:06-md-1769-Orl-22DAB2009 WL 223140 (M.D. Fla. Jan 30, 2009), The court held that the plaintiffs should be permitted to explain to the jury the implications of the drug manufacturer's misrepresentations in the creation and/or sponsorship of ghostwritten publications and other literature related to the safety and efficacy of the drug. As such, the evidence was ruled admissible. *Id.* at \*3. In *Proctor v. Davis*, 682 N.E.2d 1203 (Ill. App. Ct. 1997), an Illinois appellate court found ghostwriting evidence to be a basis for affirming a punitive damage award. In *Proctor*, the drug company paid doctors to write case reports for publication, ordered thousands of copies of these articles to be distributed to the medical community, undertook the task of 'scattering about' information to doctors promoting its drug for unapproved off-label use, and routinely forwarded copies of articles discussing unapproved uses to physicians. *Id.* at 270. The court was particularly offended because, "although it is assumed that physicians will keep abreast of current medical literature, here, part

of the flawed literature was generated by [the drug manufacturer]." *Id.* at 284. The court strongly condemned ghostwriting as a practice that should not be countenanced. *Id.*<sup>8</sup>

Similarly, in *In re Yasmin & Yaz (Drospirenone) Mktg.*, 2011 U.S. Dist. LEXIS 147935, at \*25 (S.D. Ill. Dec. 22, 2011), the court noted "In the context of this case and *the issue of adequate warning, in particular,* [evidence of ghostwriting] is *particularly relevant* for the fact finder to consider with all the other evidence in the case." (emphasis added). In denying the defendant's motion *in limine* to exclude evidence of ghostwriting, another court has noted:

Such evidence is probative of (i) defendant's failure to warn the medical community of the risks of taking Prempro; (ii) defendant's disregard for such risks, as that disregard may bear on the appropriateness of punitive damages; and (iii) the information relied upon by plaintiff's doctors when prescribing Prempro.

Torkie-Tork v. Wyeth, 2010 U.S. Dist. LEXIS 121804 at \*4 (E.D. Va. Nov. 15, 2010). See also Kammerer v. Wyeth, 2012 U.S. Dist. LEXIS 10905, at \*4 (D. Neb. Jan 31, 2012) ("the court finds there is no basis to exclude evidence of Wyeth-supported, ghostwritten literature...").

# C.. Evidence of Monsanto's Ghostwriting Is Not Overly Prejudicial.

California Evidence Code Section 352 "speaks in terms of undue prejudice. Unless the dangers of undue prejudice, confusion, or time consumption 'substantially outweigh' the probative value of relevant evidence, a section 352 objection should fail." People v.

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<sup>&</sup>lt;sup>8</sup> Many other court have admitted and considered evidence of ghostwriting. See, e.g., Giles v. Wyeth, 500 F. Supp. 2d 1063, 1064 (S.D. Ill. 2007) (motion for summary judgment on failure to warn claim denied in part because of evidence that Wyeth had "utilized material misrepresentations to promote and market is drug via the practice of 'ghost writing' scientific articles for publication under the names of prominent academic 'authors.'"); Tucker v. SmithKline Beecham Corp., 701 F. Supp. 2d 1040, 1048 (S.D. Ind. 2010)(Indiana district judge in Paxil litigation denied challenges to plaintiff's expert, in part, because expert, in forming his opinion on the drug company's negligence, appropriately relied upon the "practice of ghostwriting scientific articles, which [the expert] said has led to exaggeration of the benefits of drugs and concealment of their risks."); Strom ex rel United States of America v. Scios, Inc. 676 F. Supp. 2d 884, 888-889 (N.D. Cal. 2009) (motion to dismiss False Claims Act cause of action denied; court discussed evidence that defendant used a third party to ghostwrite articles about its drug and arranged to submit them for publication under the names of doctors selected by the defendant).

Scott (2011) 52 Cal.4th 452, 490–491 (emphasis in original) (quoting People v. Cudjo (1993) 6 Cal.4th 585, 609); People v. Yu (1983) 143 Cal.App.3d 358, 377 (when applying Section 352, "prejudicial" is not synonymous with "damaging.").

Monsanto claims that ghostwriting evidence is prejudicial because the allegations of ghostwriting are baseless. However, as demonstrated above, the allegations of ghostwriting are true and are based on Monsanto's own scientists admissions. While the evidence is certainly damaging to Monsanto, there is no indication a jury can't look at the evidence objectively. Monsanto is free to argue that when its employees say they ghostwrite articles that they didn't really mean it. Indeed, most of this evidence will come in through Plaintiff's questioning of Monsanto corporate witnesses in videotaped depositions that have already occurred. The Monsanto witnesses had a chance to explain why their actions at the deposition. Dr. Benbrook will also talk about ghostwritten articles, and Monsanto can cross examine him. This evidence goes straight to the core of Monsanto's actions in covering up the risk of Roundup®.

#### IV. CONCLUSION

For the above stated reasons, Plaintiff respectfully requests that this honorable Court DENY Monsanto's Motion *in limine* No. 20 to Exclude Evidence of Ghostwriting.

Respectfully submitted,

### THE MILLER FIRM, LLC

DATED: June 7, 2018

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