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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
Hardeman v. Monsanto Co., et al., 3:16-cv-0525-VC *Stevick v. Monsanto Co., et al.*, 3:16-cv-2341-VC *Gebeyehou v. Monsanto Co., et al.*, 3:16-cv-5813-VC	**MONSANTO COMPANY'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT RE: TIER 1 PLAINTIFFS ON NON-CAUSATION GROUNDS AND EXCLUSION OF DRS. BENBROOK, SAWYER, AND MILLS**

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INTRODUCTION

Plaintiffs' Opposition does not meaningfully engage on the merits of Monsanto's Summary Judgment Motion. Rather than come forward with substantive responses to Monsanto's arguments explaining the deficiencies in their claims and with their experts, Plaintiffs principally offer bluster. But a careful review of Plaintiffs' substantive claims and the experts they offer to support them demonstrates that neither can survive.

With respect to express and impossibility preemption, Plaintiffs concede the two ultimate points: (a) California's warnings law is ***substantively*** inconsistent with FIFRA's misbranding provisions as to foreseeable use, and (b) FIFRA prohibits Monsanto from independently making the label and design changes Plaintiffs seek without first obtaining EPA approval. Each concession confirms that their claims are preempted. Likewise, Plaintiffs cannot come forward with evidence upon which a jury could find that it was "generally accepted" when Plaintiffs used Roundup that Roundup causes cancer. Nor have they come forward with evidence from which a reasonable jury could find Monsanto acted "despicably" given the uncontroverted regulatory consensus, held to this day, that glyphosate does not cause cancer in humans. Finally, because Mr. Gebeyehou affirmatively asserted that he believed Roundup caused his NHL when he sent an email to his doctor on September 24, 2014, there is no factual dispute and his claim is time barred. Monsanto is entitled to summary judgment on all claims asserted against it by the Tier 1 Plaintiffs.

If any of these cases proceed to trial, the opinions of Drs. Benbrook, Sawyer, and Mills should be excluded under *Daubert* and F.R.E. 702. Dr. Benbrook, an agricultural economist, cannot serve as a narrator of company documents nor instruct the jury on the law and Monsanto's alleged noncompliance. Dr. Sawyer, a specific causation expert, has no opinions specific to Hardeman and Gebeyehou (indeed, he did not evaluate anything about their cases), and so there is no basis for allowing him to testify in those trials. Further, his opinions as to Stevick are the product of an unreliable methodology that is a "differential diagnosis" in name only. And Dr. Mills' opinions are not derived from scientific or specialized knowledge nor do they assist the trier of fact.

ARGUMENT

I. PLAINTIFFS' WARNINGS CLAIMS ARE EXPRESSLY PREEMPTED.

Plaintiffs argue that even if their warning claims impose requirements in addition to or different from FIFRA, summary judgment would be inappropriate and, instead, the Court could cure any "minimal inconsistencies" with a jury instruction. Plaintiffs cite one sentence from the Supreme Court's opinion in *Bates* as well as language from *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207, 222 (3d Cir. 2010) and *Adams v. United States*, 449 F. App'x 653, 659 (9th Cir. 2011) to support their position. (*See* Plaintiffs' Opposition ("Opp") at 7–8).

Plaintiffs' reliance on the language from these cases is misplaced. While a jury instruction may be sufficient to correct a "mere inconsistency" between "nominally equivalent" state and federal labeling requirements, a jury instruction cannot avoid preemption when the state law imposes requirements that are ***substantively*** different from or in addition to FIFRA's requirements. *See Adams*, 449 F. App'x at 659 (analyzing a warnings instruction to ensure that it "sufficiently track[ed] FIFRA's own requirements," but only *after* determining that Plaintiffs' failure-to-warn claims were not preempted by FIFRA).

Here, California law imposes on manufacturers significantly broader labeling requirements related to foreseeable use than FIFRA. These are not merely inconsistent, nominally equivalent requirements of the sort discussed in *Indian Brand Farms* and *Bates.* Rather, California law substantively expands label warnings requirements from FIFRA's "widespread and common uses" to risks associated with ***any*** reasonably foreseeable use or misuse. Accordingly, Plaintiffs' warnings claims are expressly preempted by FIFRA.

II. PLAINTIFFS DO NOT DISPUTE THAT IT IS IMPOSSIBLE FOR MONSANTO TO COMPLY WITH BOTH FIFRA AND THEIR TORT CLAIMS.

Plaintiffs do not contest that FIFRA, its regulations, and EPA guidance documents prohibit Monsanto from independently making the design and label changes Plaintiffs seek without first obtaining EPA's approval. (Opp. at 8-18). Because Plaintiffs concede that Monsanto cannot independently comply with both FIFRA and their tort claims, they do not contest the fundamental

basis of Monsanto's impossibility preemption argument and instead argue that impossibility preemption is categorically inapplicable to FIFRA.[1] A holding that impossibility preemption can never apply to FIFRA finds no support in the governing Supreme Court law and would turn the Supremacy Clause on its head.

A. *Bates* Does Not Make Impossibility Preemption Inapplicable to FIFRA.

Plaintiffs, relying heavily on the flawed reasoning of *Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270, 1280 (D. Haw. 2015), claim that *Bates* rejected *sub silentio* the impossibility preemption analysis articulated years later in *Wyeth*, *Mensing*, and *Bartlett*. (Opp. at 8-9). Aside from being chronologically flawed, Plaintiffs' arguments conflate Monsanto's "impossibility" preemption argument with the "field" preemption and "obstacle" preemption arguments made in *Bates*.[2]

The *Bates* Court granted *certiorari* to resolve a circuit split over whether warning claims "parallel" to FIFRA's misbranding provisions were expressly preempted under § 136v(b). *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437 (2005). In addition to express preemption, Dow argued field or obstacle preemption applied because parallel claims would disrupt FIFRA's uniform regulatory scheme. *Id.* at 447. The Court expressly rejected those arguments, but the Court did not undertake any impossibility preemption analysis. *Mutual Pharm. Co. v. Bartlett*,

[1] Plaintiffs suggest that, in addition to their label claims, they will also be making non-label claims that Monsanto failed to warn about cancer risks in marketing materials they presumably read and relied upon, which are not subject to preemption. (Opp. at 8, n.3). Plaintiffs failed to articulate with any specificity what non-label claims they relied upon. In any event, Monsanto cannot make non-label claims that are inconsistent with the Roundup label. *See* 40 C.F.R. § 168.22. EPA has clearly indicated that advertising a pesticide in a manner inconsistent with its labeling is a violation of FIFRA. *Id.*

[2] Express preemption occurs when Congress "withdraw[s] specified powers from the States by enacting a statute containing an express preemption provision." *Arizona v. United States*, 567 U.S. 387, 399 (2012). Field preemption is a type of implied preemption where "[t]he intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Id.* (citations omitted). Finally, obstacle preemption is another type of implied preemption that occurs not when compliance with both state law and federal law is impossible, but rather when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citation omitted).

570 U.S. 472, 491 (2013) (explaining *Bates* as holding that "the design-defect claim in question was not a 'requirement "for labeling or packaging"' and thus fell outside the class of claims covered by the express pre-emption provision at issue in that case."). Accordingly, *Bates* did not foreclose impossibility preemption under FIFRA.

B. Congressional Intent Is Not Relevant to Impossibility Preemption.

Plaintiffs argue at length that impossibility preemption is inapplicable because § 136v(a) of FIFRA reserves states the right to "regulate the sale or use of any federally registered pesticide" and therefore FIFRA does not manifest congressional intent to preempt state law. (Opp. at 9-10). Congressional intent, however, is not the touchstone for impossibility preemption.

Unlike express, field, and obstacle preemption that turn on the intent or objectives of Congress, *Arizona*, 567 U.S. at 399, impossibility preemption "requires no inquiry into congressional design." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963) ("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce.") (citations omitted). Rather, impossibility preemption flows from the Constitution's Supremacy Clause and occurs anytime where "compliance with both state and federal law is impossible." *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1595 (2015) (citation omitted). Indeed, in the context of the Federal Food Drug and Cosmetic Act ("FDCA") at issue in *Wyeth*, *Mensing*, and *Bartlett*, Congress had adopted a statement similar to § 136v(a) of FIRFA about preserving state law, but that provision did not affect the impossibility preemption analysis. See Pub.L. No 87-781, 76 Stat. 780, 793 (1962) ("Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) ("To the extent respondent posits that anything other than our ordinary pre-emption principles apply under these circumstances, that contention must fail in light of our conclusion last

Term in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), that neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'"). Accordingly, the absence of statutory language evincing a congressional intent to preempt state law has no bearing on impossibility preemption. *Bartlett*, 570 U.S. at 480 ("Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.'").

Plaintiffs' effort to distinguish *Bartlett* and *Mensing* because the FDCA is not an identical regulatory scheme to FIFRA is beside the point. (Opp. at 11). That FIFRA allows states to ban EPA-approved pesticides under § 136v(a) is immaterial to impossibility preemption; the FDCA similarly allows FDA to withdraw approval of a drug, but that does not mean that a manufacturer of drugs – or pesticides – can independently make the label and design for a marketed product without regulatory approval. (Mot. at 9-11). FIFRA, like the FDCA, prohibits a manufacturer from making certain product label and design changes without first obtaining agency approval. *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 9 (1st Cir. 2018) ("If a private party . . . cannot comply with state law without first obtaining the approval of a federal regulatory agency, then the application of that law to that private party is preempted."). Nor is it an answer to impossibility preemption to say that a manufacturer can comply with state law by not selling the product. *See Bartlett*, 570 U.S. at 488 (rejecting that a manufacturer can simply "stop-selling" a federally-approved product in order to avoid liability under a state law requirement).

C. *Mensing* and *Bartlett* Apply When a Private Party Cannot Comply with State Law Without First Obtaining The Approval of a Federal Regulatory Agency.

Plaintiffs rely on a divided Third Circuit panel decision in *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 714 (3d Cir. 2018) to argue that *Wyeth*'s "clear evidence" standard and not *Bartlett* and *Mensing*'s "prior agency approval" standard applies. The *Sikkelee* majority, however, improperly grafted *Wyeth*'s "clear evidence" standard onto an FAA reregulation that required agency pre-approval. *See Sikkelee*, 907 F.3d at 718 (Roth, dissenting) ("Although the Majority

opinion cogently summarizes [*Wyeth*, *Mensing*, and *Bartlett*], it fails to consider their combined import."). The majority ruling is not consistent with *Wyeth*, *Mensing*, or *Bartlett* for the reasons stated in the thoughtful dissent, nor is it consistent with the First Circuit's unanimous 2018 decision in *Gustavsen*, 903 F.3d at 9.

Wyeth's "clear evidence" standard arose in the context of FDCA's "changes being effected" ("CBE") regulation, 21 C.F.R. § 314.70(c), which authorized the drug maker to ***unilaterally*** add warnings to their drug label subject to FDA's authority to rescind or modify the label change. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). Under that type of regulation, the Court required the defendant to show "clear evidence" that FDA would have rejected a proposed warning submitted under that mechanism. *Id.* at 568–571. *Bartlett* and *Mensing*, however, apply when the applicable regulation requires the manufacturer to seek regulatory approval ***prior*** to making the label or design change.

The *Sikkelee* dissent found the distinction obvious when the cases are read as a trilogy:

> "those decisions present a cohesive standard: when federal regulations prevent a manufacturer from altering its product without prior agency approval, design defect claims are preempted; when federal regulations allow a manufacturer to independently alter its product without such prior approval, design defect claims ordinarily are not preempted."

Sikkelee, 907 F.3d at 718; *see also In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) ("The line *Wyeth* and [*Mensing*] thus draw between changes that can be independently made using the CBE regulation and changes that require prior FDA approval also makes some pragmatic sense."). One month before *Sikkelee*, the First Circuit observed that *Wyeth*, *Mensing*, and *Bartlett* read in concert means that "[i]f a private party . . . cannot comply with state law without first obtaining the approval of a federal regulatory agency, then the application of that law to that private party is preempted." *Gustavsen*, 903 F.3d at 9.

Plaintiffs, here, do not dispute that under FIFRA, its regulations, and EPA guidance documents, Monsanto cannot amend its Roundup label to add a cancer warning to the "Precautionary Statements" of the label or change the Roundup formulation without prior EPA

approval. (Mot. at 9-11). Accordingly, *Wyeth*'s "clear evidence" standard for impossibility preemption does not apply and *Mensing* and *Bartlett* should apply.

D. Even Under *Wyeth*'s Clear Evidence Standard Plaintiffs Failed to Controvert Evidence that EPA Has Consistently Rejected That Glyphosate is Carcinogenic to Humans.

Monsanto submitted an overwhelming evidentiary record showing that EPA has repeatedly determined that glyphosate is not carcinogenic, including on at least five occasions since IARC's classification. (Exs. 4-13, 15-20). Just a few weeks ago, for the sixth time since IARC's classification, EPA reiterated that "it is confident" that "glyphosate is not likely to be carcinogenic" and that its conclusion is consistent with Canadian, European Union, German, and Japanese regulators. (Stekloff Declaration filed herewith ("Stekloff Decl."), 12/21/18 EPA Letter, Ex. 25). EPA has also approved labels for glyphosate-based herbicides without cancer warnings both before IARC's classification[3][4], as well as after learning of IARC's position concerning glyphosate as shown by EPA approval letters issued in October 2016 for Roundup Custom® Herbicide[5] and February 2018 for Roundup QuikPRO®.[6] Plaintiffs do not dispute that EPA has consistently rejected the proposition that glyphosate causes cancer in humans – the essential claim in this litigation.

Plaintiffs instead contend that Monsanto's failure to propose to EPA a cancer warning for Roundup somehow precludes a finding of "clear evidence" that EPA would have rejected such a proposed warning. But, as another California court recognized, "[*Wyeth v.*] *Levine* does not premise clear evidence on manufacturer submission of a proposed warning to" EPA. *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1169 (S.D. Cal. 2016) ("The relevant inquiry in each conflict preemption case since *Levine* is stated as whether the FDA would have rejected a proposed labeling change, not whether the FDA did in fact issue an explicit rejection."). A party

[3] https://www3.epa.gov/pesticides/chem_search/ppls/000524-00517-20100125.pdf

[4] https://www3.epa.gov/pesticides/chem_search/ppls/000524-00579-20090701.pdf

[5] https://www3.epa.gov/pesticides/chem_search/ppls/000524-00343-20161018.pdf

[6] https://www3.epa.gov/pesticides/chem_search/ppls/093236-00004-20180222.pdf

can also meet the "clear evidence" evidence standard by showing the regulatory agency disagrees that a warning is scientifically supportable. *Id.* at 1170.

Courts have held that a regulatory agency's repeated and consistent conclusion that a particular product does not pose a particular risk constitutes "clear evidence" that the regulatory agency would have rejected a proposed warning related to that risk. *See id.* at 1174 ("The FDA's repeated conclusion that scientific data did not support warning of pancreatic cancer risk coupled with the FDA's statement that product labeling was adequate amounts to clear evidence that the FDA would have rejected a pancreatic cancer labeling change."); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1276–77 (W.D. Okla. 2011) (the FDA's "repeated conclusions . . . that there was no scientific evidence to support a causal connection between [selective serotonin reuptake inhibitors] and suicidality in adult patients" constituted "clear evidence that the FDA would have rejected" an expanded warning for suicide). EPA's repeated conclusions that glyphosate is not carcinogenic therefore constitute "clear evidence" that EPA would have rejected a warning related to carcinogenicity. Because Plaintiffs have not disputed this clear evidence, summary judgment is appropriate. *See id.* at 1268, 1280 (granting summary judgment where the plaintiff did not dispute the FDA's repeated conclusions).

III. PLAINTIFFS HAVE NOT COME FORWARD WITH EVIDENCE THAT IT WAS "GENERALLY ACCEPTED" IN THE SCIENTIFIC COMMUNITY AT THE TIME OF DISTRIBUTION THAT GLYPHOSATE CAUSES CANCER.

To prove a warnings claim under California law, Plaintiffs must show that it was "known or knowable in light of the scientific knowledge that was ***generally accepted*** in the scientific community at the ***time of distribution***" that Roundup can cause cancer. CACI 1205 (emphasis added). To satisfy California law, that risk must be generally accepted – not merely a minority view." *Id.*, Directions for Use ("A risk may be 'generally recognized' as a view (knowledge) advanced by one body of scientific thought and experiment, but it may not be the 'prevailing' or 'best' scientific view; that is, it may be a minority view. The committee believes that when a risk is (1) generally recognized (2) as prevailing in the relevant scientific community, and (3)

represents the best scholarship available, it is sufficient to say that the risk is knowable in light of 'the generally accepted' scientific knowledge."). Plaintiffs, who last used Roundup in 2014, failed to produce any evidence showing that it was "generally accepted in the scientific community" that Roundup caused cancer as of 2014. (Opp. at 19-20). Nor could Plaintiffs controvert Monsanto's evidence showing the inverse—that it was "generally accepted" by EPA and other worldwide regulatory agencies that Roundup did *not* cause cancer in humans. (Mot. Exs. 4-13, 15-20, 25).

Plaintiffs direct the court to a couple rodent studies from the 1980s that EPA ultimately concluded did not establish glyphosate was carcinogenetic, Dr. Parry's reports from late the 1990s concerning potential genotoxicity of glyphosate, and a single epidemiology paper. (Opp. at 20). As this court knows, however, this is a tiny fraction of the glyphosate science. (Mot. Ex. 12, EPA OPP Report at 10 ("An extensive database exists for evaluating the carcinogenic potential of glyphosate, including 63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies.")). Pointing to a few studies taken out of context cannot establish general acceptance. EPA and other agencies have regularly reviewed the entire body of science related to glyphosate and concluded again and again that glyphosate is not carcinogenic. (Mot. Exs. 4-13, 15-20, 25). Summary judgment is appropriate on Plaintiffs' warnings claims because undisputed facts show that "at the time of distribution" to Plaintiffs, Roundup's supposed capacity to cause cancer was not "known or knowable in light of the scientific knowledge that was ***generally accepted*** in the scientific community."

IV. PLAINTIFFS' PUNITIVE DAMAGE CLAIMS FAIL BECAUSE THEY DID NOT PRODUCE EVIDENCE OF "DESPICABLE" CONDUCT BY MONSANTO.

Plaintiffs cite the following evidence to support punitive damages: Monsanto's response to Dr. Parry's genotoxicity review in early 2000s (Opp. at 23-24); Monsanto's supposed "ghostwriting" of Williams (2000), Williams (2012), Kier & Kirkland (2013), and Williams (2016) (Opp. 25-27); Monsanto's alleged failure to test surfactants (Opp. at 28); Monsanto's response to IARC's classification in 2015 (Opp. 28-29); and Monsanto's conduct related to an

ATSDR review of glyphosate in 2015.[7] Because all reasonable factual inferences inure to the non-movant at summary judgment, Monsanto will not dispute in detail these purported "facts" now. But, as a threshold matter, Plaintiffs' reliance on Monsanto's conduct after they stopped using Roundup in 2014 is improper because due process requires punitive damages to be derived "from the acts upon which liability was premised." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422–23 (2003). The remaining evidence, even when afforded all favorable inferences,[8] is not sufficient for a jury to find Monsanto acted "despicably," especially when that evidence is weighed against a worldwide regulatory consensus that glyphosate is not carcinogenic and epidemiology showing no causal association.

A. Monsanto Cannot Be Punished For Conduct That Could Not Have Caused Plaintiffs' NHL.

A punitive damage award cannot be premised on "conduct that bore no relation to the [Plaintiffs'] harm" without violating federal due process. *State Farm*, 538 U.S. at 422–23 ("A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages."); *see also Willis v. Buffalo Pumps Inc.*, No. 12cv744 BTM (DHB), 2014 WL 1028437, at *5 (S.D. Cal. Mar. 17, 2014) ("Punitive damages are not simply recoverable in the abstract. They must be tied to oppression, fraud or malice in the conduct which gave rise to liability in the case."). None of the of the evidence cited by Plaintiffs that occurred after they stopped using Roundup in 2014—*i.e.*, the Williams (2016) article, Monsanto's response to IARC's classification, and the ATSDR review—could have caused Plaintiffs' NHL and, therefore, is not competent to oppose summary judgment on punitive damages.

[7] Plaintiffs also cite to trial testimony of a former Monsanto sales representative Kirk Azevedo. (Opp. 23). They omit, however, that the trial judge in Johnson granted a motion to strike that testimony: "You know what, I'm going to grant the motion to strike the Azevedo testimony regarding the statement that . . . Monsanto is about making money 'get it straight' . . . as that testimony is not relevant." (Stekloff Decl., Johnson Tr. at 4934:13-20, Ex. 26). It certainly is not a basis to impose punitive damages.

[8] Notably, Plaintiffs' punitive damages case is largely based on Dr. Parry's review of genotoxicity papers and three articles concerning genotoxicity. Genotoxicity is type of mechanistic data that, at most, is supplemental to more substantial epidemiology or toxicology evidence. *In re Roundup Prods. Liab. Litig.*, No. 16-md-02741-VC, 2018 WL 3368534, at *17 (N.D. Cal. July 10, 2018).

B. Monsanto's Response to Dr. Parry's Genotoxicity Review Was Not Improper, Let Alone Despicable.

Plaintiffs claim Monsanto acted despicably by not volunteering Dr. Parry's report about a handful of published genotoxicity papers to EPA. Plaintiffs further provide no evidence that Monsanto's failure to share the Parry report altered EPA's evaluation about glyphosate's carcinogenicity. Every piece of evidence cuts against such an inference. Monsanto performed the tests recommended by Dr. Parry concerning genotoxicity and published the results in a 2008 paper. (Mot. Ex. 21). Moreover, EPA has considered nearly 90 published genotoxicity studies for the active ingredient glyphosate, in addition to numerous epidemiology and toxicology studies relating glyphosate, in reaching its unequivocal conclusion about glyphosate. (Mot. Ex. 12, EPA OPP Report at 10). EPA reiterated just one month ago that it "is confident in its conclusion that glyphosate is not likely to be carcinogenic to humans." (12/21/18 EPA Letter, Ex. 25).

C. Monsanto's Involvement with Williams (2000), Williams (2012), and Kier & Kirkland (2013) Was Not Improper, Let Alone Despicable.

Plaintiffs suggest Monsanto acted "despicably" in supposedly "ghostwriting" three genotoxicity papers: Williams (2000), Williams (2012), and Kier & Kirkland (2013). (Opp. 25-27). First, Plaintiffs do not claim there is anything false or misleading about the data or statements contained in these articles. Nor is there any evidence that any of the data and statements in these articles had any type of negative impact on Plaintiffs. And Monsanto cannot be punished for participating in scientific debate about glyphosate. *See Board of Trs. of Leland Stanford Jr. Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) ("It is . . . settled . . . that the First Amendment protects scientific expression and debate . . . ."); *Senart v. Mobay Chem. Corp.*, 597 F. Supp. 502, 505-06 (D. Minn. 1984) ("[P]laintiffs assail defendants for taking a particular view in a scientific debate and for trying to retain a regulatory standard which defendants preferred. Not only do these actions not constitute torts, they are protected by the first amendment.").

Second, these review articles transparently reflect Monsanto's involvement, which means they were not nefariously ghostwritten in any sense relevant to punitive damages. Williams (2000)

expressly acknowledges "[k]ey personnel at Monsanto who provided scientific support" including William F. Heydens and Donna R. Farmer (Mot. Ex. 22 at 2), and the Williams (2012) publication similarly acknowledges Monsanto "for funding and for providing its unpublished glyphosate and surfactant toxicity study reports." (Stekloff Decl., Williams (2012), Ex. 27). Kier & Kirkland (2013) acknowledges "David Saltmiras (Monsanto Company)," among others, for his "contributions to this work by providing regulatory studies and [his] thoughtful review of the manuscript." (Mot. Ex. 23 at 4). Even afforded all inferences, no jury can find that Monsanto's participation in these three review articles "is so vile, base, [or] contemptible . . . that it would be looked down on and despised by ordinary decent people." *Mock v. Michigan Millers Mut. Ins. Co*., 4 Cal. App. 4th 306, 331 (1992).

D. Monsanto's Testing of Surfactants Was Not Improper, Let Alone Despicable.

Plaintiffs' insinuation that Monsanto did not perform chronic carcinogenicity testing on the surfactants used in Roundup is wrong. (Opp. at 28). Monsanto performed chronic carcinogenicity tests on the surfactants used in Roundup and submitted those tests to EPA for approval. (Stekloff Decl., Donna Farmer Dep. at 420, 429-430, Ex. 28). Monsanto simply did not perform chronic carcinogenicity tests on the formulated Roundup product, nor did EPA require that testing. Plaintiffs also fail to tie their allegations about a European regulator's inquiry into tallow amine to anything that is remotely related causally to Plaintiffs' cancer. *State Farm*, 538 U.S. at 423 ("A defendant should [only] be punished for the conduct that harmed the plaintiff . . . ."). Plaintiffs produced no evidence they were even exposed to tallow amine, let alone evidence that suggests any exposure increased their risk of NHL compared to other glyphosate-based herbicides.

E. Monsanto Reasonably Relied on Worldwide Regulatory Consensus.

In contrast to the handful of cherry-picked papers and emails Plaintiffs rely on to support punitive damages, Monsanto relied on the undisputed global regulatory consensus that glyphosate is not a human carcinogen. (Mot. Exs. 4-13, 15-20). Relying on strong epidemiological evidence and consistent regulatory approval of glyphosate is not "despicable" conduct; rather, it is reasonable corporate conduct that merits dismissal of Plaintiffs' punitive damages claims.

F. Plaintiffs Failed to Produce Evidence Showing Monsanto's Scientists Directed Roundup Corporate Policy

Plaintiffs claim that Dr. Farmer (regulatory toxicologist), Dr. Heydens (senior regulatory toxicologist), and Daniel Jenkins (regulatory affairs manager) are "managing agents" that direct Monsanto corporate policy on Roundup. Plaintiffs produced no supporting evidence as is their burden on summary judgment. Rather, the evidence they produced shows that Dr. Farmer, Dr. Heydens, and Mr. Jenkins were employees responsible for regulatory compliance and not managing agents who dictated corporate strategy.

V. GEBEYEHOU'S CLAIMS ARE INDISPUTABLY TIME BARRED.

Conceding that he suspected that Roundup was the cause of his NHL at least as early as September 24, 2014, Gebeyehou argues that his case is nevertheless timely because he had no scientific evidence to support his suspicions at that time and his doctor failed to respond to his inquiry.[9] But the standard is not whether he was aware of scientific evidence supporting a causal link between Roundup and his NHL; rather, the law is clear that "[a] plaintiff need not be aware of the specific 'facts' necessary to establish the claim; that is a process contemplated by pretrial discovery. Once the plaintiff has a suspicion of wrongdoing, and therefore an incentive to sue, she must decide whether to file suit or sit on her rights." *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1111 (1988). Here, Gebeyehou indisputably chose the latter.

Gebeyehou fails to make the factual showing mandated by the California Supreme Court in *Fox v. Ethicon Endo-Surgery, Inc.*, which noted California's "policy of charging plaintiffs with *presumptive* knowledge of the wrongful cause of an injury," to help effectuate the "general policy encouraging plaintiffs to pursue their claims *diligently*." 35 Cal. 4th 797, 808 (2005) (emphasis added). Even at the more permissive pleadings stage, if a claim is facially time-barred, a plaintiff "must specifically plead facts to show (1) the time and manner of discovery *and* (2) the inability to

[9] Gebeyehou contends that the two-year statute of limitations in Civ. Proc. Code section 340.8 is applicable here. Assuming, *arguendo*, that Section 340.8 does apply, Gebeyehou's claims fail for the same reasons outlined in the motion because Section 335.1 also provides for a two-year statute of limitations. (*See also* Opp. 50:8:10).

have made earlier discovery despite reasonable diligence." *Id.* There are no such allegations in the Complaint and no such evidence in the Opposition.

Gebeyehou claims that he conducted a "reasonable inquiry" because he sent the article describing a connection between Roundup and NHL to his doctor and his doctor rejected his suspicions. (Opp. at 51). But Gebeyehou admits that his doctor "did not respond to or address Mr. Gebeyehou's comment about Roundup and NHL." (Opp. at 52). Regardless of whether he exaggerated to his doctor that he was "95% certain" that Roundup caused his NHL, there is no dispute that Gebeyehou believed that Roundup caused or could have caused his NHL when he sent that e-mail on September 24, 2014. His failure to follow-up after his doctor did not respond only further demonstrates that he failed to act diligently in pursuing his claims.

The uncontroverted evidence also shows that Gebeyehou believed Roundup caused his NHL because he watched a Dr. Oz show describing the allegedly dangerous effects of the way he used Roundup. (Mot. Ex 1, Gebeyehou Tr. 63:9-12, 55:23-56:1). Despite his clear deposition testimony, Gebeyehou now contends that an episode that aired on September 22, 2014, did not address a specific correlation between Roundup use and NHL. But it is well settled that a non-movant cannot rely on a declaration that contradicts prior sworn testimony to defeat summary judgment. *Kennedy v. Allied Mut. Ins. Co.*, 952 F.2d 262, 266 (9th Cir. 1991). In any event, whether the episode mentioned Roundup does not change the fact that Gebeyehou believed—after watching a Dr. Oz show—that there was a direct correlation between Roundup and his NHL, which was further confirmed with his internet research.

Plaintiff's admissions are dispositive. In *Gray v. Reeves*, a plaintiff suffered an allergic reaction to a drug in 1971, but delayed filing suit against the prescribing doctor and manufacturer until 1973. 76 Cal. App. 3d 567 (1977). The court affirmed the summary judgment order for defendants based on the statute of limitations noting plaintiff's admission that in 1971 he knew that defendants "did something wrong." *Id.* at 577. The court found that even without specific facts as to why the drug was defective, the plaintiff was on notice at that time that he had a

potential cause of action. *Id.* Here, Gebeyehou suspected more than just that Monsanto did something wrong; he was "95% sure that [his] cancer [was] caused by Roundup herbicide."

Gebeyehou relies on *Clark v. Baxter Healthcare Corp.*, 83 Cal. App. 4th 1048 (2000), to assert that the discovery rule should apply because IARC had not classified glyphosate as a 2A carcinogen until March 20, 2015.[10] But *Clark* is inapposite. There, the court found a disputed issue of fact because "[t]he record could support an inference that [the plaintiff] did not become aware of a potential wrongfulness component of her cause of action until more information than the existence of her allergies placed her on inquiry notice and then was actually gained." *Id.* at 1060. Here, no inference is necessary because Gebeyehou indisputably stated that Roundup caused his NHL. Whether IARC had classified glyphosate as a 2A carcinogen does not bear on whether Gebeyehou had knowledge of his claims.

Finally, Gebeyehou's assertion that equitable tolling should apply due to Monsanto's purported fraudulent concealment should be rejected. Again, Gebeyehou explicitly stated in writing more than two years prior to filing this complaint that he believed Roundup caused his NHL. Monsanto's actions have nothing to do with this analysis because Gebeyehou still had knowledge of his claims. There are no disputed issues of fact, and the Court should enter judgment in favor of Monsanto.

VI. REPLY IN SUPPORT OF MOTION TO EXCLUDE DR. CHARLES BENBROOK.

The court in *Johnson* largely excluded Dr. Benbrook, holding that he did not possess the requisite "familiarity with the EPA or Monsanto's internal knowledge or regulatory compliance." (*See Johnson* Order at 30 (ECF 2417-3)). The vast majority of his opinions usurped the jury's fact-finder role and improperly opined on legal issues. Accordingly, the court limited Dr. Benbrook's testimony to only "the general framework of the EPA regulatory decision making process." Plaintiffs here simply make the same flawed arguments rejected in *Johnson*.

[10] Gebeyehou's suggestion that he could not have "discovered" Roundup's carcinogenicity until IARC announced its classification in March 2015 is entirely inconsistent with his positon that Monsanto should have warned of cancer risks because it was "generally accepted in the scientific community" as of 2014.

A. Dr. Benbrook Lacks the Necessary Qualifications.

Dr. Benbrook is an economist who has never worked at any regulatory agency (including EPA) or any pesticide manufacturer. Plaintiffs claim his role as a "staff director" for a legislative subcommittee in the early 1980s qualifies him to testify. But Dr. Benbrook admitted that he had no direct responsibility for regulating pesticides in that decades-old legislative position. (*See* Benbrook *Johnson* Dep. at 85:9-11 (ECF 2417-4)). Plaintiffs also claim Dr. Benbrook is qualified because he runs a private consulting business and recently wrote an article on glyphosate. (Opp. at 35). These recent endeavors do not substitute for Dr. Benbrook's lack of relevant education, experience and expertise, and they certainly do not cloak him with the required experience and expertise necessary to testify on complex scientific issues or to offer his opinions and interpretations of Monsanto documents and corporate conduct. Like the court in *Johnson*, this Court too should exercise its gatekeeping function and exclude Dr. Benbrook's opinions for failure to meet the threshold qualification requirement.

B. Dr. Benbrook's Personal "Interpretation" of Monsanto Documents and Opinions on Corporate Ethics are Inappropriate Topics for Expert Testimony.

Plaintiffs cannot avoid the well-settled law that an expert is not permitted to opine regarding the intent, motive, or state of mind of a corporation. While purporting to disclaim any such intention, they nevertheless claim that Dr. Benbrook should be permitted to testify about "factual matters that properly inform the jury's own determination of motive, intent, or state of mind." (Opp. at 36 (emphasis removed)). This creative attempt to avoid the prohibition on expert testimony about corporate intent is a distinction without a difference.

The vast majority of Dr. Benbrook's proposed testimony as laid out in his report consists of his narrations or "interpretations" about how various internal Monsanto documents purportedly demonstrate Plaintiffs' liability themes, usually by purporting to discern motives from his review of documents: *e.g.*, Monsanto valuing profits over safety, Monsanto ghostwriting review papers in an effort to manipulate regulators, and Monsanto responding to new scientific developments with

the motive to preserve market share rather than to understand the science. (*See* Benbrook Rpt. at ¶¶ 16, 88, 105, 106 430 (ECF 2417-2)).

These summaries of company documents are not "merely statements of fact in the record," as Plaintiffs claim. (*See* Opp. at 37). They are slanted "interpretations" and fall squarely within the province of the jury as the fact-finder. Nor are they so "complicated" that they require explanation by an expert, and Plaintiffs do not offer a single example of a purported "complicated" document. (*Id.*). There is nothing so complicated about these documents—as opposed to other documents at issue in this trial—that require expert explanation. The jury is fully capable of reviewing the documents at issue, assessing them, and finding facts about them. That is, in fact, the entire point of a jury trial, and juries routinely evaluate corporate documents to determine facts without the aid of an expert. Plaintiffs point to nothing special, unusual, or complicated here that makes these documents any different.[11]

Dr. Benbrook's opinions on corporate ethics and whether Monsanto acted as a "responsible" or "ethical" manufacturer should also be excluded. Not only are these opinions inappropriate topics for expert testimony,[12] but as an economist who has never been employed by a pesticide manufacturer or the EPA, Dr. Benbrook does not possess the requisite qualifications to offer opinions on the standard of care applicable to Monsanto. In this regard, his "opinions" are nothing more than an attempt to instruct the jury on Monsanto's legal duties—a function held by this Court, not a partisan expert.

[11] Even if expert testimony were required to explain Monsanto's corporate documents, Dr. Benbrook is not a properly qualified expert for that purpose, as he has *never* worked at any pesticide manufacturer or at the EPA and has no specialized or relevant experience interpreting corporate documents of this type. *See White v. Ford Motor Co.*, 312 F.3d 998, 1008-09 (9th Cir. 2002).

[12] *See, e.g.*, *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495187, at *3 (D. Ariz. Jan. 22, 2018) ("Personal views on proper corporate behavior are not appropriate expert opinions.").

C. Dr. Benbrook's Opinions on Monsanto's Compliance With Legal or Regulatory Duties Usurp the Jury's Function and Should Be Excluded.

Plaintiffs make clear that, if left unchecked, Dr. Benbrook intends to substitute his opinions for that of the jury and testify on the ultimate issues in this case, including "that Monsanto had a duty to warn consumers of the risk of NHL." (*See* Opp. at 38-39). But testimony drawing legal conclusions central to a case—particularly by a witness who is not a legal expert—is routinely excluded. *See, e.g.*, *Lukov v. Schindler Elevator Corp.*, No. 5:11-cv-00201 EJD, 2012 WL 2428251, at *2 (N.D. Cal. June 26, 2012) (excluding expert testimony on legal issue); *United States v. Smith*, 573 F.3d 639, 655 (8th Cir. 2009) ("[I]t is 'the judge and not a witness' that 'is to instruct the fact finder on the applicable principles of law.'"). Plaintiffs ignore this key fact-finding function of the jury. *See City of New York v. FedEx Ground Package Sys., Inc.*, No. 13 Civ. 9173 (ER), 2018 WL 4961455, at *4 (S.D.N.Y. Oct. 15, 2018) (excluding expert opinion where expert "relied on the same types of evidence that a jury traditionally relies upon to answer the sort of question that a jury traditionally answers."). The jury can—and must—review the evidence itself.

Plaintiffs' counsel wants to use Dr. Benbrook as a conduit to put their own spin on Monsanto's documents and compliance with its legal obligations under the guise of "expert" testimony. But the jury is fully capable of, and in fact is charged with, evaluating the evidence and determining Monsanto's compliance with legal obligations, and Dr. Benbrook lacks the requisite qualifications in any event. His proffered expert testimony should be excluded.

VII. REPLY IN SUPPORT OF MOTION TO EXCLUDE DR. WILLIAM SAWYER

A. The Court Should Not Permit Dr. Sawyer To Testify In the *Hardeman* and *Gebeyehou* Cases.

Plaintiffs all but concede that there is no basis for allowing Dr. Sawyer to testify in *Hardeman* or *Gebeyehou*. There can be no debate that Plaintiffs proffered Dr. Sawyer as a specific causation expert—the sole conclusion in his expert report is that "Mrs. Stevick's exposure to Roundup was a substantial factor that contributed to her development of NHL." Sawyer Rep.

121. And it is undisputed that Dr. Sawyer has no specific causation conclusions regarding Mr. Hardeman or Mr. Gebeyehou. He did not interview either of them, review their medical records or deposition testimony, or conduct an analysis of their Roundup exposure. Outside of the cover page, his report does not mention Mr. Hardeman or Mr. Gebeyehou at all. And Dr. Sawyer admitted that he did no analysis of their cases because he did not have enough time. (Sawyer MDL Dep. Tr. 32:11-19 (ECF 2418-4)). In fact, he told Plaintiffs' counsel that such an analysis was "not humanly possible in the time window that was presented, so all [he] could agree to was assessing the general toxicological factors that apply to anyone and apply to the other plaintiffs. There just wasn't time to do a full analysis as [he] did on Ms. Stevick with respect to the other two plaintiffs." *Id.* at 32:13-19.

Plaintiffs' only response ignores clear Ninth Circuit case law about what it means to provide specific-causation testimony. Plaintiffs assert that Dr. Sawyer's opinions "on issues concerning the mechanism of absorption of glyphosate-based formulations through the skin and other exposure pathways and the effect of wearing personal protective equipment on the exposure levels . . . directly address[] critical issues relevant to specific causation." *Id.* But as the Ninth Circuit has made clear, specific or "'individual causation' refers to whether a *particular individual* suffers from a particular ailment as a result of exposure to a substance." *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002) (emphasis added). This determination is highly individualistic, depending on the characteristics of the individual plaintiffs and the nature of the plaintiffs' exposure. *Id.* (citing *In re Agent Orange Prod. Liab. Litig. MDL No. 381*, 818 F.2d 145, 165 (2d Cir. 1987)). And Dr. Sawyer has acknowledged that his opinions regarding the "toxicological mechanism effects of the glyphosate [sic] with respect to absorption, excretion, co-formulates [sic] and contaminants," (Opp. 41 n.45), do not meet this standard. He has confirmed that these opinions are not specific to any plaintiff, and do not account for any plaintiff's individual characteristics and exposures. (*See* Sawyer MDL Dep. Tr. 194:2-7 (ECF 2418-4)). In fact, in another case involving Roundup, Dr. Sawyer has actually admitted that these are *general causation* opinions: "I'm going to explain the properties, the absorption, distribution, metabolism,

and the carcinogenicity aspects of glyphosate and Roundup super concentrate. Q. Okay. And so you only plan to offer a general causation opinion that it's your opinion glyphosate-based herbicides can cause cancer, correct? A. Yes, but as I said a moment ago, relative to other potential carcinogens." (Sawyer *Hall* Dep. Tr. 480:14-23 (ECF 2418-10)).[13]

Plaintiffs' effort to rebrand Dr. Sawyer as an "exposure" expert on their witness lists changes nothing. Again, the sole conclusion in Dr. Sawyer's report is a specific causation opinion as to Mrs. Stevick. He had nothing to say about Mr. Hardeman or Mr. Gebeyehou's exposure—nor did he attempt to analyze those issues in any way—and so any conclusions on those matters would be improper. *See, e.g., Therasense, Inc. v. Becton, Dickinson & Co.*, No. C 04-02123 WHA, 2008 WL 2037732, at *4 (N.D. Cal. May 12, 2008) (referring to the "paramount rule that all experts will be limited on direct examination to the four corners of their report"). Any testimony he could offer would relate to general causation, not specific causation, and the time has passed for new testimony in that area. *See* Stekloff Decl. Ex. 29, 12/5/18 MDL CMC Tr. 29:2-19; *In re Hanford*, 292 F.3d at 1135 ("[W]here the distinction" between general and specific causation "is made, it must be strictly observed.").

B. The Court Should Exclude Dr. Sawyer's Specific-Cause Opinion As To Ms. Stevick.

As Monsanto argued in its opening brief, Dr. Sawyer's specific-cause opinion as to Ms. Stevick is inadmissible because it relies upon an improper differential diagnosis, an epidemiological analysis beyond Dr. Sawyer's expertise, and an unreliable methodology. Plaintiffs offer no convincing reason why that opinion meets *Daubert*'s "exacting standards," *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000). (*See* Opp. 41-45).

First, Plaintiffs wrongly insist that Dr. Sawyer utilized a proper differential diagnosis method to reach his conclusions as to Ms. Stevick. (Opp. 41). But merely invoking the term

[13] Plaintiffs' assertion that this testimony has been deemed "helpful" in other cases is misleading at best. *See* Opp. 39-40 (citing *Whitlock v. Pepsi Americas*, 527 F. App'x 660 (9th Cir. 2013)). In *Whitlock*, Dr. Sawyer was proffered as an expert on both general and specific causation, and even there, the Court observed that his "[s]haky but admissible" opinions should be attacked on cross examination. *Id.* at 661-62 (quoting *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010)).

"differential diagnosis" is insufficient to survive *Daubert* (and it bears repeating that Dr. Sawyer never used that term until his deposition). *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 551 (W.D. Pa. 2003). Nor does it suffice for Dr. Sawyer to "conduct[] a thorough review of Mrs. Stevick's family history, age; prior work history; operational hazards; home hazards; alcohol, tobacco, and drug history; and medical history." (Opp. 41). As the Court well knows, an expert conducting a differential diagnosis must "accurately diagnose the nature of the disease, reliably rule in the possible causes of it, and reliably rule out the rejected causes." *In re Aredia & Zometa Prods. Liab. Litig.*, 483 F. App'x 182, 188 (6th Cir. 2012). Here, Dr. Sawyer "ruled in" Roundup based on his cherry-picked analysis of a handful of epidemiological studies purportedly showing that Roundup exposure for more than two days increased NHL risk. *See, e.g.*, Sawyer Rep. at 27-28 (ECF 2418-3); Sawyer MDL Dep. Tr. 42:2-43:11 (ECF 2418-4) (describing how exposure-day threshold was derived from two epidemiological studies); 231:7-233:7 (confirming that his specific-causation opinion is based primarily on Ms. Stevick's exposure days). As Monsanto has explained, that is not a valid basis for ruling in Roundup as a cause for a particular plaintiff. *See Lust ex rel. Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996) (noting that experts cannot pick and choose from the scientific landscape).

That is especially so because Dr. Sawyer lacks the expertise to assess the epidemiological studies on which his purported "differential diagnosis" depends. *See, e.g.*, Sawyer MDL Dep. Tr. 42:2-43:11; 231:7-233:7 (ECF 2418-4). In direct contradiction to Plaintiffs' claim that Dr Sawyer is qualified to utilize epidemiology in this manner, (Opp. 43), Dr. Sawyer himself has disclaimed any epidemiological expertise. *See, e.g.*, Sawyer MDL Dep. Tr. 199:11-20 (ECF 2418-4) ("Q Yeah, but when I asked you what you were relying on to conclude that more likely than not Mrs. Stevick's cancer was not the result of an idiopathic cause, you referenced -- or you testified that that's based on the epidemiologic studies I've referenced, which included McDuffie 2001 and Eriksson 2008. What other epidemiologic studies are you relying on to conclude that more likely

than not Mrs. Stevick's cancer was not the result of an idiopathic cause? A I'm deferring that to the epidemiologists.).

Nor did Dr. Sawyer reliably complete the second part of the differential diagnosis analysis—ruling out other potential causes of NHL. Plaintiffs quote Dr. Sawyer's bald assertions that other chemicals and radiation could not have caused Ms. Stevick's NHL. (*See* Opp. 42-43). But they do not, and cannot, dispute that Dr. Sawyer did not quantify Ms. Stevick's exposure to these known NHL risk factors. *Compare* Sawyer MDL Dep. Tr. 85:2-4 (agreeing ionizing radiation is a risk factor) *and id.* 87:14-17 (agreeing mecoprop is a risk factor), *with id.* 119:25-19 (explaining that he did not quantify Ms. Stevick's occupational exposure to ionizing radiation) *and id.* 117:14-17 (explaining that he did not quantify her mecoprop exposure). And while Plaintiffs obliquely mention that Dr. Sawyer "took into account" idiopathic causes, Dr. Sawyer himself admitted that the "entire basis" for ruling out such causes was that Ms. Stevick cleared his Roundup-exposure-day threshold. Sawyer MDL Dep. Tr. 198:15-199:25 (ECF 2418-4). That is at best circular reasoning, and not a proper differential diagnosis. *See Avila v. Willits Envtl. Remediation Tr.*, 633 F.3d 828, 838 (9th Cir. 2011) (expert opinion inadmissible where expert "simply assumed that causation existed without going through the steps in the differential diagnosis process that his report said he would"). In the end, Dr. Sawyer offers the same "always-Roundup" analysis as Plaintiffs' other specific causation experts.

Second, with regard to Dr. Sawyer's use of the UK Predictive Operator Exposure Model (the "POEM"), Plaintiffs argue what is not in dispute: that the POEM is a "generally accepted pesticide modeling technique" used internationally and by Monsanto. (Opp. 43-44). Plaintiffs entirely dodge the question of the POEM's applicability to *Mrs. Stevick*: They fail to explain how using the *regulatory* POEM, which Dr. Sawyer admits systematically overestimates exposure, Sawyer MDL Dep. Tr. 205:14-206:12 (ECF 2418-4), and is not calibrated for glyphosate, *see* Sawyer *Hall* Dep. Tr. 437:7-11 (ECF 2418-10), is appropriate to estimate Ms. Stevick's *residential* glyphosate exposure. Likewise, Plaintiffs do nothing to justify Dr. Sawyer's results-driven selection of POEM inputs that are inconsistent with the published literature. *See* Sawyer

MDL Dep. Tr. 261:9-13 (ECF 2418-4) ("Are you able to name a dermal absorption study in human skin where the study authors themselves reported a dermal absorption value higher than 2 percent? A No."); *Lust*, 89 F.3d at 598. Because Dr. Sawyer's analysis is the product of flawed scientific methods, it should be excluded.

C. The Court Should Exclude Dr. Sawyer's Remaining Opinions, Which Exceed His Expertise or Are Untimely.

The parties agree that Dr. Sawyer lacks expertise to opine as to Monsanto's corporate intent. (*See* Opp. 45). Nor is there any basis for allowing Dr. Sawyer to interpret terminology used in corporate emails. Dr. Sawyer's toxicological expertise affords him no special skill in interpreting a Monsanto employee's interpretation of a scientific term or study, and there is no need for experts to interpret emails that speak for themselves.

Monsanto also believes, like Dr. Sawyer himself, that Dr. Sawyer is not qualified to opine on Monsanto's compliance with any ethical obligations—he removed any such opinions from his report in this case.[14] On this matter, Plaintiffs reliance on *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 3806436, at *4 (M.D. Fla. July 20, 2009) is misplaced. (Opp. 45). Though the court in that case permitted an expert to testify regarding corporate documents for a specific and limited purpose, *id.* at *4, it also held that an expert was not allowed to "render any opinions regarding the state of mind, intent, motives or ethics of AstraZeneca or any of its employees," because such "matters are not the proper subject of expert opinion; they are matters to be argued by counsel based on the evidence," *id.* at *5.

Finally, there is no basis for allowing Dr. Sawyer to offer untimely rebuttal opinions. Remarkably, rather than addressing Monsanto's argument that these untimely opinions are inadmissible, Plaintiffs in their opposition have offered yet another new opinion: Exhibit 74 to

[14] *See, e.g.*, Opp. Ex. 74 ¶ 94 ("[I]f a Defendant communication contains a seeming ethical violation, it is my belief that the court and jury will make up their own minds about such matters."); Sawyer MDL Dep. Tr. 267:20-24 (ECF 2418-4) ("So if you go to page 72 of your Johnson report and page 97 of your Stevick report, you see on page 72 you have a whole paragraph there where you discuss ethical quandaries? A Yeah. I removed that."); Sawyer *Hall* Dep. Tr. 42:18-19 (ECF 2418-10) ("Q. Are you an ethicist? A. No.).

their opposition is a 32-page "rebuttal" declaration from Dr. Sawyer. (Opp. Ex. 74 at 3-5). But the solution for offering untimely rebuttal opinions is not more untimely rebuttal opinions. Dr. Sawyer should not be permitted to flout the court's scheduling orders, as already has been his habit in this and other cases in this circuit. *See Avila*, 633 F.3d at 835-36 (affirming district court's decision to strike *Dr. Sawyer's untimely declaration* because the late opinions contained therein "could and should have been furnished by the deadline" (emphasis added)). Dr. Sawyer's untimely rebuttal opinions, like all his opinions in this litigation, are improper, unreliable, and inadmissible.

VIII. REPLY IN SUPPORT OF MOTION TO EXCLUDE MR. JAMES MILLS

Plaintiffs' response regarding purported economic expert Mr. James Mills confirms exactly why his exclusion is warranted. Plaintiffs seek to bolster Mr. Mills' economic credentials, but the relevant point under *Daubert* is Mr. Mills' acknowledgement—time and again—that the methodology he applied *in the case* required *no* economic training or knowledge, but simple regurgitation of financial numbers from Monsanto's public filings. *E.g.*, Mot. to Exclude Mills, Ex. 2, at 33:13-19 ("Q. You did not do any analysis to reach these [net sales] numbers, right? A. Correct. They're taken as reported. Q. And no economic training was required to find these [net sales] numbers in Monsanto's financial reports? A. No. They are published and printed there."). Courts have repeatedly excluded experts that engage in such rudimentary, copy-paste analysis. *See Israel Travel Advisory Serv., Inc. v. Israel Identity Tours, Inc.*, No. 92 C 2379, 1993 WL 387346, at *2 (N.D. Ill. Sept. 23, 1993) (excluding testimony from CPA that did not rely on his "training or experience," but calculations that could be performed "by anyone with junior high school mathematics."); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008), *aff'd in relevant part*, 586 F.3d 547 (8th Cir. 2009) ("Having an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony."). "Opinion given through the mouth of an expert does not necessarily make it *expert* opinion." *Id.* (emphasis in original); *see also* Mot. at 4 (collecting cases).

Nor does it benefit Plaintiffs to argue that a defendant's financial condition is relevant to the punitive damages inquiry. (Opp. at 47-48). Setting aside whether punitive damages are even available here, Mr. Mills has not performed any economic analysis that will *assist* the jury to understand the issue.[15] That is what distinguishes this case from *In re Yasmin*, the main authority Plaintiffs cite. (Opp. at 48-49). There, the court permitted testimony from a financial expert who reviewed both public and private financial documents, undertook the conversion of all figures into U.S. currency, and applied "generally-accepted economic formulas" to arrive at a calculation of "total wealth," a number that is not otherwise reported in financial documents. *In re Yasmin & YAZ Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2011 WL 6732819, at *7 & n.7 (S.D. Ill. Dec. 16, 2011). Mr. Mills, by contrast, did nothing of the sort—he simply took numbers from public documents and transcribed them into his report. His testimony accordingly should be excluded.

CONCLUSION

For the foregoing additional reasons, Monsanto respectfully requests that the Court grants its motion to exclude opinion of non-causation experts Benbrook, Sawyer, and Mills and also grant its motion for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure and dismiss these cases in their entirety with prejudice.

[15] Plaintiffs' argument that Mr. Mills's testimony will assist the jury because he can provide "interpretation and analysis" of Monsanto's "full financial condition," Plfs.' Opp. at 48, finds no basis in Mr. Mills' report, which does nothing more than list a series of financial figures. *See, e.g.*, *Therasense*, 2008 WL 2037732, at *4 (referring to the "paramount rule that all experts will be limited on direct examination to the four corners of their report").

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 1st day of February 2019, a copy of the foregoing was served via electronic mail to opposing counsel.

/s/ *Brian L. Stekloff*