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In The California Court of Appeal
First Appellate District
Division One

Dewayne Lee Johnson,
Plaintiff and Respondent/Cross-Appellant,
v.
Monsanto Company
Defendant and Appellant/Cross-Respondent

APPEAL FROM THE SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF SAN FRANCISCO
HONORABLE SUZANNE R. BOLANOS

Respondent/Cross-Appellant's Supplemental Briefing on Preemption Questions

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I. INTRODUCTION

The issue of preemption has been briefed and argued extensively among the multiple state and district courts presiding over Roundup product liability claims. Those courts have *unanimously* found "that FIFRA does *not* preempt [failure-to-warn] claims for damages under state law." *Blitz v. Monsanto Company* (W.D. Wis. 2018) 317 F.Supp.3d 1042, 1049.

Judge Karnow, in denying Monsanto's preemption defense, understood that "the touchstone of the preemption analysis is Congress' intent in enacting FIFRA." 4-AA-3212. Accordingly, Judge Karnow properly focused his preemption analysis on FIFRA; not the FDCA. In doing so, Judge Karnow properly followed the dictate that courts should "not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme." *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 626. The Court should affirm Judge Karnow's well-reasoned opinion. 4-AA-3207-3212. It was correct when it was issued, and it is correct now.

But, this Court should answer its third question first, because the issue of whether the "clear-evidence" preemption standard of *Wyeth v. Levine* (2008) 555 U.S. 555, applies to Johnson's failure to warn claim is moot if the Court decides that his design defect claims are not preempted. *Arnold v. Dow Chemical Co.* (2001) 91 Cal.App.4th 698, 727 (pre-*Bates* decision concluding that design-defect claims based on consumer expectation test are not preempted); *Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431, 444 ("It is perfectly clear" that design defect claims are not preempted). If the Court agrees that the Supreme Court's unanimous ruling that under FIFRA "it is perfectly clear" that the design defect claim is not preempted, the verdict stands, and judicial restraint dictates that courts "not reach constitutional questions unless absolutely required to do so to dispose of the matter before us." *Santa Clara County Local Transportation Authority v. Guardino* (1995) 11 Cal.4th 220, 230 (quoting *People v. Williams* (1976) 16 Cal.3d 663, 667).

Regarding Question One, nothing done by the EPA in 2019 warrants a different result with respect to Johnson's failure-to-warn claim. The U.S. Supreme Court even holds that a jury verdict *at odds* with EPA findings—the crux of Monsanto's impossibility argument—does not pose a preemption problem. *Bates,* 544 U.S. at 452 ("While it is true that properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding, there is no reason to think such occurrences would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that every day bear the risk of conflicting jury verdicts.").

In analyzing preemption on the failure to warn claims, the Court correctly notes Judge Karnow's finding that "it does not appear that any court has extended *Wyeth* to FIFRA." The purpose of *Bates* was to rectify the improper attempts by lower courts to create similar pre-emption schemes across dissimilar statutory schemes. For at least a decade before the passage of FIFRA, arguments that tort cases were preempted "either were not advanced or were unsuccessful." *Id.* at 441. Lower courts only began finding that FIFRA preempted tort cases by improperly applying the Court's rationale for preemption under the Public Health Cigarette Smoking Act of 1969 in *Cipollone v. Liggett Group, Inc*., (1992) 505 U.S. 504. *Id. Bates* held that the lower courts erred in applying *Cipollone* to FIFRA because they were not "paying attention to the rather obvious textual differences between the two pre-emption clauses." *Id.*

Monsanto initially agreed that implied preemption was not applicable under *Bates*. In *Hardeman v. Monsanto*, Monsanto argued that the "clear evidence" standard is "inapposite" within the FIFRA preemption context. *See Hardeman v. Monsanto,* (N.D. Cal. Mar. 22, 2016) No. 3:16-cv-005250VC at 6-7, 2016 WL 8652587. Monsanto emphasized it was making "no such implied preemption argument" and that "[t]he preemption issue

before the Court in this case is governed by Bates, not Wyeth..." *Id.*

Monsanto now reverses course and asks this Court to ignore the Supreme Court's clear instruction in *Bates* that, when considering preemption, lower courts must consider FIFRA's statutory language instead of relying on cases analyzing other statutes. The Court should decline Monsanto's request to ignore the Supreme Court's admonition in *Bates*. There are several obvious textual differences between FIFRA and the FDCA that preclude application of an impossibility preemption analysis under FIFRA. For example, "In relying on a line of FDCA cases, Monsanto elides a critical aspect of FIFRA's statutory scheme: FIFRA allows states to regulate or ban pesticides that have been federally approved..." *In re Roundup Products Liability Litigation* (N.D. Cal. 2019) 364 F.Supp.3d 1085, 1088. Because FIFRA contemplates that states may ban the sale of pesticides and restrict their uses beyond EPA requirements, it is inconceivable that Congress intended to implicitly preempt state common-law tort suits.

> As held by the D.C. Circuit Court of Appeals, implied preemption:
>
> ...would exist only if FIFRA were viewed not as a regulatory statute aimed at protecting citizens from the hazards of modern pesticides, but rather as an affirmative subsidization of the pesticide industry that commanded states to accept the use of EPA-registered pesticides. That interpretation of FIFRA, however, is precluded by both the explicit savings clause at 7 U.S.C. § 136v(b) and by the entire legislative history of the Act.

Ferebee v. Chevron Chemical Co. (D.C. Cir. 1984) 736 F.2d 1529, 1542–1543. (*Ferebee* was cited with approval by *Bates*, 544 U.S. 431).

As to Question Two: if the Court was to apply FDA cases to FIFRA then it would apply the *Wyeth/Merck* clear evidence test. The Honorable Judge Barry Goode, in *Caballero,* undertook a thorough analysis of impossibility preemption under *Merck*, including the new EPA statements, and concluded "...on the current record, it appears that an impossibility

defense must fail." *Caballero v. Monsanto,* Case No. MSC19-01821 (Super. Ct. Alameda) (Jan. 24, 2020) at pp. 40-41 (Johnson's 1/29/20 RJN, Exhibit A). Here, likewise, the record on appeal is sufficient for the Court to reject Monsanto's impossibility preemption defense without remand to the trial court. *In re Avandia Marketing, Sales and Products Liability Litigation* (3d Cir. 2019) 945 F.3d 749, 757.

Under *Merck*, a defendant must provide clear evidence that: 1) it asked for any and all label changes that would comply with state law; 2) that it fully informed an agency of the justification; 3) the agency formally rejected the defendants application; and 4) the rejection was a final agency action with the force of law. *Merck v. Albrecht* (2019) 139 S.Ct. 1668, 1678. Monsanto fails each element of the *Merck* test. It never asked for a label change, it withheld key data, it failed to test its product, and it marshalled enormous resources and influence to prevent a label change. *See Infra,* p. 24. The EPA has also never formally rejected a request to add a cancer warning to a Roundup label on the basis that NHL is a potential risk of Roundup.

II. ARGUMENT

A. Question (3) If a court were to determine that FIFRA preempts Johnson's failure-to-warn causes of action under *Wyeth,* but not Johnson's design-defect cause of action, what effect, if any, would that have on the jury's verdict? A. Under the doctrine of judicial restraint the Court should not reach the preemption analysis on failure to warn.

For Johnson's design defect claim, the Court need only look to *Bates* which states that it is "perfectly clear" that design defect claims are not preempted. *Bates,* 544 U.S. at 444. FIFRA only preempts "requirements" for "*labeling or packaging*" if they are "*in addition to or different from* those required" under FIFRA. *Bates,* 544 U.S. at. 443–444 (quoting 7 U.S.C. § 136v(b)). Johnson's design defect claims would not qualify as requirements for labeling even if they "would surely induce a manufacturer to alter its label

to reflect a change in the list of ingredients or a change..." *Id.* at 445-446. As Judge Karnow correctly held, *Bates "*does not preempt design defect claims" and "Monsanto cannot ignore Congressional intent by pressing a theory of conflict preemption." 4-AA-3212. Even before *Bates*, it was clear that California design defect claims based on the consumer expectation test were not expressly preempted. *Arnold*, 91 Cal.App.4th at 716.[1]

Johnson's design defect claims, based on the consumer expectations test, are *not* mere reiterations of his failure to warn claims. Failure-to-warn claims are about defects in the product *label*—specifically, the omission of any warning that Roundup causes cancer. The design-defect claim, in contrast, is *not* about the label; it considers whether the product fails to "perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." *Id.* Just as in *Arnold*, "the gravamen of [Johnson's] complaint is that a consumer would reasonably believe that pesticides are designed to [kill weeds] without causing significant harm to the humans. Thus, appellants' complaint concerns a matter 'outside the label.'" *Id.* at 717.

Here, Johnson reasonably believed Roundup was safe and would not harm humans. 18B-RT-3234:20-3235:5; 3283:6-11. This is not about the label; it's about the *design of the product.* There is simply no valid reason for Roundup as formulated and designed to even be used or marketed for use at schools. Indeed, many school districts stopped using Roundup once they were disabused of any expectation of safety. 6-AA-6425. *Arnold*, 91 Cal.App.4th at 716 ("Appellants' claim is that, due to the content and properties of the products, they cannot safely be used in the home. Period.

[1] *Arnold* also rejected implied preemption because the "existence of an express preemption clause supports an inference that implied preemption is foreclosed." *Id.* at 728.

Thus, the remedy sought is a change in design of the products.") [2]

Because the design-defect claim has nothing to do with the product's label, preemption is not even an issue with regard to that claim. That should end the analysis right there. Preemption is a constitutional issue and courts "do not reach constitutional questions unless absolutely required to do so to dispose of the matter before us." *Santa Clara County*, 11 Cal.4th at 230 (quoting *Williams* 16 Cal.3d at 667). "A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them." *Lyng v. Northwest Indian Cemetery Protective Ass'n* (1988) 485 U.S. 439, 445.

Since the design defect claim is not preempted there is simply no reason to further consider whether *Wyeth* would apply to warning claims under FIFRA. The verdict would stand on a design defect claim alone.

B. Question (1) Should *Wyeth* be extended to FIFRA, such that a court should determine whether there is clear evidence the EPA would not have approved a change to the labels of Monsanto's glyphosate-based products? A. No, Bates forecloses any inquiry into impossibility preemption.

Judge Karnow highlighted three key FIFRA provisions, absent from the FDCA, that precluded application of "Wyeth and its progeny" to this case. 4-AA-3209-3212. 1) FIFRA contains an express preemption clause which manifests Congressional intent as to the scope of preemption; 2)

[2] While it is not Plaintiff's burden to demonstrate an alternative design. Monsanto certainly could have sold safer formulations of Roundup to Johnson. 21A-RT-3626:15-3627:16; 21A-RT-3609:14-3623:2 (Dr. Sawyer detailing the toxicity of surfactants in Roundup). In 2008, Monsanto debated whether to defend the surfactant used in Roundup because as one of Monsanto's scientists noted "there are non-hazardous formulations, so why sell a hazardous one?" 6-AA-6564. Monsanto recognized that the "surfactant played a role" in promoting tumors in a 2010 study. 6-AA-6537. Europe has banned the genotoxic surfactant used in the U.S. version of Roundup. 5-AA-5781.

FIFRA allows states to independently restrict and ban the use of EPA-approved pesticides; and 3) "Under the express terms of the statute, EPA approval of a pesticide is not a defense for the commission of any offense under FIFRA..." *Id.* For the following reasons, Judge Karnow is correct.

The U.S. Supreme Court has emphasized that "'the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth*, 555 U.S. at 565. (quoting *Medtronic, Inc. v. Lohr*, (1996) 518 U.S. 470, 485). A preemption analysis must be "moored tightly to the specific preemption clause at issue" *Mills v. Giant of Maryland, LLC* (D.D.C. 2006) 441 F.Supp.2d 104, 107, aff'd (D.C. Cir. 2007) 508 F.3d 11 (rejecting application of *Bates* to the FDCA because "[t]he scope of FDCA's preemption clause is much broader than FIFRA's"). The Court must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565. In interpreting statutes, Court's "have a duty to accept the reading that disfavors pre-emption."' *Bates*, 544 U.S. at 449.

In enacting FIFRA, Congress allowed States to "regulate the sale or use of any federally registered pesticide..."7 U.S.C. § 136v(a) *Id.* Congress made its intent clear that "generally, **the intent of the provision is to leave to the States the authority to impose stricter regulation on pesticides** uses than that required under the Act." Sen.Rep. No. 838 92d Cong., 2d Sess. 30 (1972)(emphasis added). The 1972 amendments to FIFRA were also intended to address growing environmental concerns and "strengthen existing labeling requirements and ensure that these requirements were followed in practice." *Wisconsin Public Intervenor v. Mortier* (1991) 501 U.S. 597, 613.

Monsanto's eleventh-hour impossibility preemption argument, rejected by *Bates* and *Ferebee*, is predicated upon a misplaced assumption that FIFRA and the FDCA are similar statutes. But in stark contrast to

FIFRA's decentralized scheme designed to preserve states' police powers—including the express authority to ban the sale of any pesticide outright—the FDCA's regulatory scheme is highly centralized. Through the FDCA, "Congress vested sole authority in the FDA to determine whether a drug may be marketed in interstate commerce." *Gross v. Pfizer*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) (*citing* 21 U.S.C. § 301 *et seq.*,).

Unlike FDCA impossibility preemption, which turns on a manufacturer's inability to comply with federal law in the face of conflicting state requirements, FIFRA expressly contemplates that states can disallow what EPA permits. See 7 U.S.C. § 136v. As Judge Karnow concluded, Monsanto's argument that it may have to stop selling Roundup in "California does not demonstrate a conflict between state and federal law. Rather, it describes a situation that is expressly approved by federal law." 4-AA-3212.

"It is highly unlikely that Congress endeavored to draw a line between the type of indirect pressure caused by a State's power to impose sales and use restrictions and the even more attenuated pressure exerted by common-law suits." *Bates*, 544 U.S. at 446; *Ansagay v. Dow Agrosciences (D. Hawaii 2015) 153 F.Supp.3d 1270, 1283*. ("A state's ability to ban or restrict the use of an EPA-approved pesticide clearly undercuts Dow's sweeping contention that any state law that impedes Dow's ability to sell its registered product runs afoul of FIFRA.") *In re Roundup Products Liability Litigation* (N.D. Cal. 2019) 364 F.Supp.3d 1085, 1088 ("But if California can stop Monsanto from selling Roundup entirely, surely it can impose state-law duties that might require Monsanto to seek EPA approval before selling an altered version of Roundup in California.")

Judge Karnow also concluded that "*Wyeth* and its progeny" do not apply to FIFRA because, unlike the FDCA, "Congress has spoken" about the scope of preemption under FIFRA with an express preemption clause. 4-AA-3210. *Ansagay* 153 F.Supp.3d at 1284 ("[b]ecause the FDCA did not contain

an express preemption provision, the Court turned to implied conflict preemption."). Judge Karnow is correct. Where "Congress has expressly identified the scope of the state law it intends to preempt" courts should "infer Congress intended to preempt no more than that absent sound contrary evidence." *Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 945. *Bates* held that "a state-law labeling requirement is not expressly preempted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. The test is straight-forward—state law and FIFRA are "equivalent" when a violation of state law would also violate FIFRA's misbranding provisions. *Id.* at 454. To the extent Johnson's common law "failure-to-warn claims attack Roundup's product labeling, they are consistent with FIFRA" and not preempted. *Hardeman v. Monsanto Company* (N.D. Cal. 2016) 216 F.Supp.3d 1037, 1038.

FIFRA thus authorizes "concurrent authority of the Federal and State Governments in this sphere." *Bates,* 544 U.S. at 451. As the Supreme Court explains:

> Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law. The imposition of state sanctions for violating state rules that merely duplicate federal requirements is equally consistent with the text of § 136v.

Bates, 544 U.S. at 442. It is "FIFRA's labeling requirements" that states can enforce. *Id.* at 447. They are not limited to enforcing the decisions of EPA. California can independently enforce FIFRA because "protection of pesticide users and victims by *both* federal and state law lies at the center of the Act's design." *Ferebee*, 736 F.2d at 1543. Furthermore, States may enforce FIFRA through jury trials because "FIFRA's authorization to the States leaves the allocation of regulatory authority to the 'absolute discretion'

of the States themselves." *Mortier*, 501 U.S. at 608. *Bates* emphasizes, "that lay juries are in no sense anathema to FIFRA's scheme: In criminal prosecutions for violation of FIFRA's provisions, see § 136*l* (b), juries necessarily pass on allegations of misbranding." 544 U.S. at 452.

Bates rejected the proposition that juries and states must agree with the EPA as to whether a label is adequate to protect health. Indeed, *Bates* emphasized that "tort suits can serve as a catalyst" in identifying risks of pesticides not yet recognized by the EPA. *Bates,* 544 U.S. 431, 451. *Bates* explained that, "... a state tort action of the kind under review may aid in the exposure of new dangers associated with pesticides*." Id. (*quoting *Ferebee,* 736 F.2d 1529). Judge Chhabria agreed finding that:

> ...the EPA's authority to enforce FIFRA does not prohibit private litigants from also enforcing that statute: the Supreme Court, rejecting an argument against "giv[ing] juries in 50 States the authority to give content to FIFRA's misbranding prohibition," *Bates,* 544 U.S. at 448, 125 S.Ct. 1788, has instead allowed "[p]rivate remedies that enforce [FIFRA's] misbranding requirements,"

Hardeman, 216 F.Supp.3d at 1038.

A California jury can therefore find that a product is misbranded under FIFRA even where the EPA does not. "FIFRA states that '[i]n no event shall registration of [a pesticide] be construed as a defense for the commission of any offense under this subchapter.' 7 U.S.C. § 136a(f)(2)" *Carias v. Monsanto* (E.D.N.Y. 2016,) 2016 WL 6803780, at *3. And "if the EPA's registration decision is not preemptive, it follows that the factual findings on which it relied in making that decision also are not preemptive." *Hernandez v. Monsanto* (C.D. Cal. 2016)) 2016 WL 6822311, at *8. Section 136a(f)(2) precludes a finding that impossibility preemption is applicable under FIFRA because EPA's action related to the registration of pesticides could never constitute an agency action with the "force of law" required by *Merck. See e.g. Carias,* 2016 WL 6803780 at *5.

Where Congress has expressly allowed for disagreements between the States and the EPA under FIFRA, it cannot be said that Congress impliedly forbade such disagreements. Congress' decision to allow states to independently enforce FIFRA necessarily envisions situations where states find violations of FIFRA and the EPA does not. Indeed, the EPA labeling manual specifically contemplates that California Prop 65 warning might conflict with federal labeling standards and tells companies how to avoid that conflict:

> 4. Related information on California Proposition 65 warnings ...If the Prop 65 term would conflict with the EPA signal word, then registrants should use "Notice" or "Attention" for the Prop 65 statement so that it does not conflict with the EPA signal word.

EPA, Label Review Manual, Chapter 7-4.[3]

The U.S. Supreme Court has twice interpreted FIFRA and rejected implied preemption claims. *Wisconsin Public Intervenor v. Mortier* (1991) 501 U.S. 597, 613 ("Nor does FIFRA otherwise imply pre-emption."); *Bates*, 544 U.S. 431; *In re Roundup*, 364 F.Supp.3d at 1088 ("Although the [*Bates*] decision centered on the scope of FIFRA's express preemption provision, the implied preemption question was also before the court... the Court necessarily rejected the possibility of implied preemption.").

Impossibility preemption was addressed by both parties in *Bates* and "the majority opinion indicates that the *Bates* Court rejected impossibility preemption *sub silentio*." *Ansagay*, 153 F. Supp. 3d a1281 (D. Haw. 2015) (citing *Dennis v. Higgins*, 498 U.S. 439 (1991) (noting implicit rejection of argument concerning relief). "It makes no sense to think otherwise. The Bates Court was reversing the court of appeals' preemption decision and had to consider any arguments that, if successful, would have affirmed the

[3] https://www.epa.gov/sites/production/files/2018-04/documents/chap-07-mar-2018.pdf

lower court decision finding preemption." *Id.* *Ansagay* conducted a detailed analysis of the *Bates* briefing and concluded "Implied conflict preemption, including impossibility conflict in particular, was indeed before the *Bates* Court." *Id.* Justice Thomas agreed noting "[the *Bates*] decision thus comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption." *Bates*, 544 U.S. at 459 (Thomas concurring in judgment and dissenting in part)

Under *Bates*, whether a jury verdict may induce Monsanto to seek a label or change or stop selling Roundup (as formulated) in California is irrelevant to preemption. Instead that is a question "that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants." *Id*. at 445. *Ferebee*, likewise considered and rejected impossibility preemption arguments under FIFRA:

> ....Maryland can be conceived of as having decided that, if it must abide by EPA's determination that a label is adequate, Maryland will nonetheless require manufacturers to bear the risk of any injuries that could have been prevented had Maryland been allowed to require a more detailed label or had Chevron persuaded EPA that a more comprehensive label was needed. The verdict itself does not command Chevron to alter its label—the verdict merely tells Chevron that, if it chooses to continue selling paraquat in Maryland, it may have to compensate for some of the resulting injuries...Chevron can comply with both federal and state law by continuing to use the EPA-approved label and by simultaneously paying damages to successful tort plaintiffs such as Mr. Ferebee.

736 F.2d at1541. What companies "cannot do, however, is to force states, under the purported aegis of a statute aimed at protecting against the hazards of modern pesticides, to accept the use of [pesticides] and to tolerate uncompensated injuries to that state's citizens." *Id.* at 1543.

Immunizing pesticide manufacturers from common law liability is plainly inconsistent with FIFRA. See id. at 449-450; 7 U.S.C. § 136j(a)(1)(E); § 136a(f)(1) (a manufacturer may seek approval to amend its

label); § 136a(f)(2) (registration not a defense to misbranding); § 136v; 40 C.F.R. §§ 159.184(a), (b) (pesticide manufactures have a duty to report incidents involving a pesticide's toxic effects that may not be adequately reflected in the product's label). Under Monsanto's theory, a manufacturer would have virtually no incentive to correct its labeling concerning human health hazards if it could rely on registration to avoid liability. This illogical result stands in direct contravention to Congress' intent in enacting FIFRA. *Bates*, 544 U.S. at 450-451 ("...it seems unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability.")

The EPA's current claim[4] that it has exclusive authority to determine whether pesticide labels are misbranded constitutes an attempt to usurp power specifically reserved for states by Congress and eviscerates Congress's intent to "leave to the States the authority to impose stricter regulation on pesticides." *See Supra.* The EPA erroneously asserts that it is undisputed "that FIFRA does not require a warning on Roundup's label that glyphosate causes cancer." Amicus Brief at 19. *Hernandez,* 2016 WL 6822311, at *6 ("administrative determinations made in approving a registration" are not requirements for a label under *Bates*). EPA officials may not require a warning on Roundup's label, but FIFRA requires that a pesticide label "contain a warning or caution statement which may be necessary and if complied with ... is adequate to protect health and the

[4] Courts do not owe deference to Amicus briefs submitted by federal agencies. In fact, *Bates,* in rejecting a preemption argument from an EPA amicus brief, stated that "[t]he notion that FIFRA contains a nonambiguous command to pre-empt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today." *Bates*, 544 U.S. at 449; *Etcheverry v. Tri-Ag Service, Inc.* (2000) 22 Cal.4th 316, 330 (rejecting EPA's position in an amicus brief that failure to warn claims are not preempted).

environment." 7 U.S.C. § 136(q)(1)(G). Three California juries have now concluded that the Roundup label violates FIFRA because it is not adequate to protect human health. As the EPA concedes "FIFRA does not prevent a State from making the violation of federal labeling requirements a state offense and imposing separate sanctions." Amicus Brief at 16.

Where the EPA fails to ensure that these requirements are followed "the statute leaves ample room for States and localities to supplement federal efforts." *Mortier,* 501 U.S. at 613. Here, the EPA has utterly failed to ensure that Monsanto has complied with FIFRA's labeling requirements. The State of California need not abide by the EPA's "disrespect[] of the scientific process"[5] and may provide remedies to its citizens for Monsanto's violations of FIFRA. *Bates,* 544 U.S. at 448 ("nothing in §136v(b) precludes States from providing such a remedy.").

Finally, the plain language of FIFRA evinces the unambiguous intent of Congress to preserve states' traditional and broad police powers. *See Bates*, 544 U.S. at 449-450. As the Supreme Court explains, "[t]he long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates* 544 U.S. at 449-450. *Bates* recognizes that the history of tort litigation "emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." *Id.*

In enacting FIFRA to protect human health, Congress refused to place "a *ceiling* on the ability of states to protect their citizens." *Ferebee*, 736 F.2d 1529, 1543. This Court should decline Monsanto's request to create a new

[5] https://oehha.ca.gov/proposition-65/general-info/oehha-statement-regarding-us-epas-press-release-and-registrant-letter

rule that would bestow blanket immunity upon manufacturers of registered pesticides. Such a rule would undermine both the goal of FIFRA's regulatory regime and the interests of states in ensuring the safety of their residents. In short, it would be completely antithetical to congressional intent.

C. Question (2) Assuming that *Wyeth* applies, is this a determination that should be made by this court in the first instance or on remand in the trial court? And whichever court makes the determination, how should it be made? Answer: The determination should be made by this Court, and this Court should conclude that there is no clear evidence of impossibility.

1. The "Clear Evidence" Determination Should be Made By This Court.

If the Court were to analyze impossibility preemption, then Johnson agrees that the "clear evidence" test would apply. *See e.g. Sikkelee v. Precision Airmotive Corporation*[6] (3d Cir. 2018) 907 F.3d 701, 713. Monsanto's burden in proving "clear evidence" is a heavy one. *See Wyeth,* 555 U.S. at 573 (the clear evidence preemption "is a demanding defense.").

Merck highlights four hurdles a company must overcome to succeed on an impossibility preemption defense. A defendant must show by clear evidence that: 1) "...it fully informed the [Agency] of the justifications for the warning required by state law; 2) "that the [Agency], in turn, informed the []manufacturer that the [Agency] would not approve changing the drug's label to include that warning;" 3) The proposed warnings must constitute "any and all warnings to the drug label that would satisfy state law;" and 4) the agency action rejecting the warning must carry the "force of law..."*Merck,* 139 S.Ct. at 1678-1679. The "possibility of impossibility" is

[6] In *Sikkelee,* the Third Circuit undertook an impossibility preemption analysis involving the Federal Aviation Administration (FAA) —a regulatory regime that plainly reserves to the states considerably fewer traditional police powers than does FIFRA— and held that *Wyeth*, guides the court's preemption analysis. 907 F.3d at 711.

not enough. *Id.* at 1678-1679. "The conflict must be real" and involve a situation where the FDA "communicate[d] its disapproval of a warning by means of notice-and-comment rulemaking" or by "formally rejecting" a proposed label change in a complete response letter. *Crockett v. Luitpold Pharmaceuticals,* (E.D. Pa., Jan. 28, 2020) 2020 WL 433367, at *7. (quoting *Merck* 129 S.Ct. at 1679.)

As explained below, the record in this case makes clear that Monsanto cannot satisfy any of the requirements under *Merck* to succeed on an impossibility preemption. The Court can therefore deny Monsanto's preemption arguments without remanding back to Judge Karnow.[7] The Court's review of Judge Karnow's summary judgement opinion regarding preemption is no different than a review of any other summary judgement opinion. *See e.g. In re Avandi*a, 945 F.3d at 757 (reversing trial court and holding "that the Plans' state-law consumer-protection claims are not preempted by the FCDA..." under the *Merck* test.)

2. The Court Should Find that Monsanto Has Failed to Meet its Burden of Showing Clear Evidence of Impossibility.

a. Monsanto Never Asked for a Cancer Warning and Never Fully Informed the EPA of the Basis for a Cancer Warning

Merck requires that a defendant must show by clear evidence that "...it fully informed the [Agency] of the justifications for the warning required by

[7]It is highly unlikely Judge Karnow would have granted summary judgment for Monsanto on impossibility preemption where the evidence supported a finding that Monsanto "...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-AA-3214. Judge Smith in *Pilliod* rejected impossibility preemption because "Monsanto's efforts to impede, discourage, or distort the scientific inquiry about glyphosate raise the issue of whether there could have been clear evidence that the EPA would have denied the hypothetical application if Monsanto had not made efforts to impede the scientific inquiry" *Pilliod v. Monsanto* Co., 2019 WL 3540107, at *9 (Cal.Super.).

state law" *Merck*, 139 S.Ct. at 1678-1679. Monsanto fails this test. Monsanto admits that it "never petitioned the EPA to revise the labeling for any of its glyphosate containing products to include a warning for NHL." 2-AA-1785. Having never requested a label change, Monsanto cannot say it fully informed the EPA of the basis for a label change and was refused a label change in any period before or during Johnson's use in 2012 to 2015. The Court's impossibility preemption analysis need go no further.

Moreover, the undisputed evidence from this case demonstrates Monsanto has never fully informed EPA of the cancer risk of Roundup. For starters, Monsanto admits it has never submitted the report of world-renowned genotoxicity expert Dr. James Parry, concluding that Roundup was potentially genotoxic and that critical tests should be performed, to the EPA. 10-RT-1587:15-1588:2. Instead, to support the current labeling of Roundup, Monsanto submitted ghostwritten articles to the EPA such as Williams (2000) which claimed that Roundup is neither genotoxic nor carcinogenic and became an "invaluable asset for response to agencies [and] regulatory reviews" RA336. In 2013, Monsanto ghostwrote another article that was to "be a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic." 6-AA-6604. In 2015, Monsanto initiated plans to ghostwrite more articles to "[p]rovide additional support ('air cover') for future regulatory reviews." RA344. This ghostwritten literature engineered by Monsanto and submitted to the EPA pervades the regulatory reviews of glyphosate. *See e.g.* 7-AA-7117; X/ARB 33-34.

Beyond that, we know that Monsanto cannot have "fully informed" the EPA about the risks of Roundup because Monsanto has not "fully informed" *itself* about whether Roundup causes cancer. Monsanto has *admitted* that "you cannot say that Roundup does not cause cancer [because] … we have not done carcinogenicity studies with 'Roundup.'". 6-AA-6466. Monsanto cannot claim that the EPA is fully informed where there are tests

that could be done, *but have yet to be done*. *Accord In re Avandia*, 945 F.3d at 759 ("By arguing that it did not have the FDA's requested data and information until *after* the FDA issued its letter, however, GSK is, in effect, conceding that the FDA was not "fully informed" at the time of the Letter's issuance."); *Wyeth*, 555 U.S. at 570 ("Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug.").

Monsanto further admits that it "has not conducted a study designed to examine specifically whether an association exists between glyphosate-containing formulations and non-Hodgkin's lymphoma." 22A-RT-3850:8-3852:2. Monsanto admits that it "has not conducted a chronic toxicity study of any of the glyphosate-containing formulations sold in the United States as of June 29, 2017." *Id.* The evidence is also clear that Monsanto did not conduct all of the genotoxicity studies recommended by Dr. Parry in 1999. 6-AA-6358-6360, 6377; 5-AA-5844-5855;13A-RT-1997:19-22. These admissions are critical. They show that Monsanto has turned a blind eye toward the potential cancer risks of its deadly product. That being so, it cannot be said that Monsanto "fully informed" EPA of all the reasons why a cancer warning should have been on the label of the product that injured Mr. Johnson.

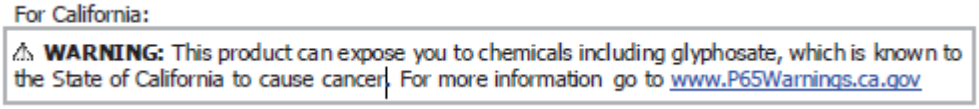
Monsanto's failure to study the cancer risks posed by Roundup is nothing short of shocking in light of what the company knew and when it knew it. In 1997, Monsanto's epidemiologist, Dr. Acquavella, emphasized the importance of conducting an epidemiology study on Monsanto's manufacturing employees who handle glyphosate due to the problems with the design of the AHS study. 6-AA-6236-6238. Twenty years later, the lack of a manufacturing worker study was identified as "a critical data-gap" by the EPA Scientific Advisory Panel evaluating glyphosate. RA-135. Panel members felt such a study was "vital to the review process" and suggested

that "because of its importance, the Agency should consider obtaining data on a cohort study of such workers for revision of the Agency's evaluation." RA-147. The EPA's analysis of the epidemiology of glyphosate plainly states that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data." 7-AA-7441. Monsanto has exclusive control over the data necessary to conduct a manufacturing worker study; yet it does not even report to the EPA incidents of Monsanto employees who develop NHL. AA5657.

Monsanto could have conducted carcinogenicity tests on the Roundup formulation; Monsanto could have conducted the tests Dr. Parry recommended; and Monsanto could have conducted the vital epidemiological study of its workers. Monsanto chose not to. Because the company never fully studied the cancer risks of Roundup, it cannot claim it fully informed the EPA about the justification for including a cancer warning on Roundup's label. *Merck*, 139 S.Ct. at 1678-1679.

b. The EPA has Never Informed Monsanto it Would Reject a Cancer Warning for Roundup

Merck requires that a defendant prove by clear evidence that after considerations of defendant's request to change a label, the agency "informed the [] manufacturer that the [Agency] would not approve changing the drug's label to include that warning." *Merck*, 139 S.Ct. at 1678-1679**.** Monsanto cannot show that the EPA has ever formally rejected a request for a cancer warning for Roundup and certainly not during the relevant time period that Johnson used Roundup. In fact, on September 6, 2017, the EPA **approved a request** by Ragan and Massey (a glyphosate manufacture) to add the following warning to its glyphosate label:



This approval proves conclusively that it was possible to add a cancer

warning to the Roundup label. Johnson's 1/24/2020 RJN, Ex. A, p. 13. This approval was not a mistake (as contended by the EPA), it underwent multiple levels of reviews. *Id.* at 2, 3, 16, 22, 25.

The Court's preemption analysis must be limited to the events at the time of the injury. In *In re Avandia,* the Third Circuit rejected the defendant's impossibility defense on the basis that post-injury the FDA ultimately concluded "that a link between Avandia use and increased cardiovascular risk does not exist." based on new data. *In re Avandia,* 945 F.3d at 756–757. "The date the operative act or omission occurred is the date for determining which preemption provision applies." *Martin*, 198 Cal.App.4th at 1410. Even under the FDCA, these "informal policy opinion[s]" made "only after [plaintiff's] injuries" have no preemptive effect. *Fellner v. Tri-Union Seafoods, L.L.C.* (3d Cir. 2008) 539 F.3d 237, 355. Judge Goode also held that post-injury agency actions are not preemptive and declined to find that "the pronouncements of 2019 merely state what had been EPA' s unchanged position since the Carter Administration." Plt.'s. 1/29/20 RJN, Ex. A. p. 41.

For example, the EPA wanted Monsanto to add a cancer warning to the Roundup label in 1985. 22A-RT-3851:13-83. In 2015, the EPA approved public dissemination of warnings about glyphosate and NHL. The National Pesticide Information Center "a cooperative agreement between Oregon State University and the U.S. Environmental Protection Agency" that "provides objective, science-based information about pesticides and pesticide-related topics to enable people to make informed decisions about pesticides and their use" was warning in 2015 that "[s]ome studies have associated glyphosate use with non-Hodgkin lymphoma." 3-AA-2903-2904. Under EPA guidelines, companies are allowed to add the NPIC hotline to their labels as a means to provide customers safety information about the pesticides. *Id.* Monsanto did not. 6-AA-6516; 6-AA-6519.

To the extent that the EPA's August 7, 2019 letter has any relevance

to this case, it is far from sufficient to carry Monsanto's burden of showing that EPA would reject the cancer warning advocated by Plaintiff. *Merck* requires clear evidence that the FDA would reject "any and all warnings to the drug label that would satisfy state law." Here, the EPA letter applies only to a very narrow set of warnings (and only in 2019). The EPA letter applies only to warnings **"exclusively on the basis that it contains glyphosate**" Defs.' Notice of Supplemental Authority, Exhibit, p. 2. However, Plaintiff's claim in this case is that the formulated product Roundup[8] (which contains other carcinogens in addition to glyphosate) more likely than not causes NHL. 4-AA3214 (Judge Karnow noting that Plaintiff provided evidence that "Monsanto has long been aware of the risk that its glyphosate-based herbicides are carcinogenic, and more dangerous than glyphosate in isolation.") The EPA has never even reviewed a carcinogenicity study of the surfactant used in Roundup. 21A-RT-3614:8-3615:25. In any event, the EPA granted the requests by companies such as Ragan & Massey to add a cancer warning based on the carcinogenicity of glyphosate alone.

The EPA letter also applies only to the exact language from Prop 65 that "this product can expose you to chemicals including glyphosate, which is known to the State of California to cause cancer." Monsanto could have applied for a milder warning to satisfy California law. Here, the EPA only states that its August 2019 letter reflects a belief that only "a **strong** glyphosate cancer warning on a pesticide label is misbranding." EPA Amicus Brief at 26. Monsanto does not have to warn that Roundup is known to cause cancer. Under California law, Monsanto need only provide "sufficient warnings of potential risks." 29A-RT-5046:22-25.

c. The EPA's August 2019 Letter does not have the Force of Law.

The August 2019 EPA letter does not constitute an agency action

[8]The EPA wrongly states that plaintiffs' claims are limited to the "active ingredient called glyphosate." Amicus Brief at 2.

which would have the force of law sufficient to preempt Johnson's claims. Even under the FDA regulatory scheme which allows impossibility preemption (unlike FIFRA), agency actions must be conducted through "congressionally delegated authority" to have any preemptive effect, such as through "notice-and-comment rulemaking setting forth labeling standards." *Merck*, 139 S.Ct. at 1679[9]. Judge Thomas noted in his concurring opinion that even where the FDA sent a letter rejecting a manufacturer's label change, the manufacturer still could have requested a hearing or provided more information, and as such "the letter was not a final agency action with the force of law, so it cannot be 'Law' with pre-emptive effect." *Id.* at 1683.

Furthermore, agency letters that eschew statutory requirements such as "notice-and-comment rulemaking" have no preemptive effect. *Reid v. Johnson & Johnson* (9th Cir. 2015) 780 F.3d 952, 964. In *Fellner* (cited with approval in *Reid*) the Third Circuit held that a letter from the FDA to California stating that a Prop 65 warning on defendant's product would be false and misleading had no preemptive effect on a plaintiff's failure to warn claim against that defendant. 539 F.3d at 254. The FDA's letter merited a "particularly low level of deference" as it was "offering a legal theory for the litigation in California." *Id.* at 251. *Fellner* held that the FDA "must actually exercise its authority in a manner in fact establishing the state warning as false or misleading under federal law" to have preemptive effect. *Id.* at 255.

[9] To the extent *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 929, provides that informal action is sufficient for preemption, it has been overruled by *Merck*. However, the issue in *Dowhal* involved the FDA utilizing its congressionally delegated authority to formally reject portions of a citizen's to include a Prop 65 warning on nicotine replacement therapies. *Id*; *see* 21 C.F.R. § 10.30 (providing formal proceedings for citizen's petitions). The FDA required some of the Plaintiffs' requested warnings, just not the exact language of Prop 65. *Id.* at 922. The FDA had legitimate concerns that the language would "discourage the women from stopping smoking." *Id.* at 929.

A statement by the FDA that it would reject a label change is not enough. And like here, the defendants also failed to prove it was impossible to add a more moderate warning than that required by Prop 65. 539 F.3d at 255-256.

Even if impossibility preemption applied, the EPA's August 2019 would not have the force of law under FIFRA because it failed to comply with congressionally delegated authority. If the EPA believes that glyphosate labels with Prop 65 warnings are misbranded, then there is "a detailed, multi-step process that EPA *must* follow." *Reckitt Benckiser, Inc. v. Jackson* (D.D.C. 2011) 762 F.Supp.2d 34, 42. In initiating the process with manufacturers the EPA's only options are to issue "a notice of intent to cancel [with a right to a hearing] or issue a notice of intent to hold a hearing on cancellation..." *Id.* at 43. The EPA did not utilize either of these mandated options. The EPA cannot reject a request for a label amendment without full procedural protections including a notice and comment period, and a full hearing (which would be subject to judicial review). 7 U.S.C. § 136a(c)(6); 7 U.S.C.. § 136d; 7 U.S.C § 136n. The EPA has not established that a Prop 65 warning is false and misleading; it has not even started the process.

If the EPA ever does formally reject a request to add a cancer warning, then Monsanto could certainly utilize the due process protections under FIFRA and even seek judicial review of that rejection. Unless and until Monsanto makes use of the procedural protections embodied in FIFRA, and fully presses its case for a cancer warning, there is no agency action with the force of law. To date, Monsanto has done everything in its power to prevent the EPA from adding a cancer warning to the Roundup label. X/ARB 40-49.

3. Monsanto Can Warn Through Means Other than the EPA Label.

The Court should not limit its analysis of preemption to the EPA label as FIFRA is not the only federal law at issue in this case. Under OSHA, companies are required to provide professional users of Roundup, such as Johnson, with Material Safety Data Sheets. Monsanto employees agree there

is a "federal law requiring that we list IARC on our material safety data sheet." 5-AA-5646; 21A-RT-3637:2-11 (Dr. Sawyer explaining the same). Monsanto even added a warning to the safety data sheets that "that IARC classifies glyphosate as a 2A probable human carcinogen, but that we do not concur with this assessment." 5-AA-5647. (This was put on after Johnson stopped using Roundup). Johnson relied on these safety data sheets prior to the addition of the cancer warning. 18B-RT-3230:10-3232:4.

OSHA provides that "manufacturers ... must treat ... IARC monographs, "as establishing that a chemical is a carcinogen *or potential carcinogen* for hazard communication purposes." *Styrene Information & Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal.App.4th 1082, 1099 (citing 29 C.F.R.1910.1200 (d)(4) (2012)). However, under OSHA, Monsanto did not have to wait for IARC to add cancer warnings to the safety data sheet; it could have applied IARC's criteria and added its own warning prior to 2012 when Johnson stated using Roundup. 29 C.F.R. §1910.1200 (APPENDIX A.6).

Monsanto can also comply with California law by warning consumers through means other than the product label. For example, "[M]anufacturers need not feel pressure to apply for EPA approval of label changes so that they can comply with Proposition 65. Point-of-sale signs are sufficient to satisfy the California requirements." *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 947 (pre-*Bates* opinion holding that Prop 65 is not preempted). Additionally, "claims for non-label-related marketing efforts are not preempted, even to the extent that those claims are based in part on failure to warn." *In re Dicamba Herbicides Litigation,* (E.D. Mo. 2019) 359 F.Supp.3d 711, 735; *Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.* (3d Cir. 2010) 617 F.3d 207, 218 ("District Court erred when it concluded that Novartis's marketing brochure qualified as "labeling" under FIFRA.") *New York State Pesticide Coalition, Inc. v. Jorling* (2d Cir.

1989) 874 F.2d 115, 119 ("Notification requirements such as cover sheets, signs, and newspaper advertisements do not impair the integrity of the FIFRA label. Rather, they serve to further the purpose of the statute by enlisting state aid to prevent "unreasonable adverse effects [of pesticide use] on the environment." 7 U.S.C. § 136a(c)(5).")

Therefore, Monsanto could have complied with California law (even without asking the EPA for a label change) by posting warning signs at Johnson's place of work; or at the store where Johnson bought Roundup. Monsanto could have instructed the Roundup sales reps to tell Johnson that Roundup caused cancer at training sessions instead of telling him it was "safe enough to drink." 18B-RT-3229:9-3230:9. Instead of leading an "unprecedented coordinated efforts to undermine the [IARC] evaluation, the program and the organization," Monsanto could have coordinated its media efforts to raise public awareness of the potential cancer risk of Roundup. 16A-RT-2597:12-18. But, Monsanto elected instead to do nothing.

III. CONCLUSION

This Court need not reach the preemption issue as the verdict stands on the finding of strict liability. The controlling precedent of *Bates* negates any need to analyze the FDA line of cases. Even if Monsanto had offered a plausible reading of FIFRA's pre-emption reach, "we would nevertheless have a duty to accept the reading that disfavors pre-emption. [B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Bates*, 544 U.S. at 449. Johnson's verdict should be affirmed.

February 11, 2020

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I am employed in the County of Orange, Commonwealth of Virginia. I am over the age of 18 years and not a party to the within action. My business address is 108 Railroad Avenue, Orange, VA 22960.

On February 11, 2020, I served the foregoing documents described as Motion for Judicial Notice and Proposed Order on all interested parties in this action as follows:

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Via the Court's TrueFiling Electronic Filing System.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on February 11, 2020, at Orange, VA.

Jeffrey A. Travers