IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT, DIVISION ONE

DEWAYNE JOHNSON, Plaintiff and Appellee/Cross-Appellant, **v.** **MONSANTO COMPANY**, Defendant and Appellant/Cross-Appellee.	Case Nos. A155940 & A156706

Appeal from the Superior Court of the State of California, County of San Francisco
The Honorable Suzanne R. Bolanos

BRIEF OF THE CALIFORNIA ATTORNEY GENERAL AS AMICUS CURIAE IN SUPPORT OF PLAINTIFF

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INTRODUCTION

This appeal raises the question whether plaintiff's California common law tort claim for failure to warn is preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a statute that "preserves a broad role for state regulation." (*Bates v. Dow Agrosciences LLC,* (2005) 544 U.S. 431, 450.)

On January 21, 2020, the Court requested supplemental briefing on the issue of preemption. At the heart of the Court's questions is whether *Wyeth v. Levine* (2009) 555 U.S. 555 and its progeny apply in the FIFRA context and, if so, whether it was impossible for Monsanto to comply with both federal and state-law requirements such that state-law requirements must give way.

The Court's order also granted Monsanto's request for judicial notice of a brief filed by the United States Environmental Protection Agency (EPA) as amicus curiae in the U.S. Court of Appeals for the Ninth Circuit in *Hardeman v. Monsanto* (Case Nos. 19-16636), a case involving substantially the same claims and the same arguments as this case. The EPA's brief argues that FIFRA preempts claims under state law for failure to warn, emphasizing the EPA's approval of a label for a glyphosate-based pesticide containing no cancer warning and highlighting an EPA official's subsequent letter to pesticide registrants stating EPA's view that labels bearing Proposition 65 cancer warnings based on the presence of glyphosate would be "misbranded" under FIFRA. Despite the fact that the plaintiff in *Hardeman*, like Mr. Johnson in this case, raised only state common law claims, the EPA's brief argues that the agency's actions related to glyphosate preempt not just common law claims, but also claims under Proposition 65.

The EPA's broad view of FIFRA preemption, both express and implied, is not correct. EPA's brief, of which this Court has taken judicial

notice, argues that the plain terms of FIFRA expressly preempt state pesticide-labeling requirements such that the issue of implied preemption need not be reached. FIFRA does not expressly displace claims under Proposition 65 of similar state common law claims because those state laws do not impose any requirement in addition to or distinct from the requirements imposed by FIFRA itself. Furthermore, FIFRA's express preemption provision is limited to "labeling and packaging," and therefore would not apply to point-of-sale warnings that may be otherwise permitted or required under Proposition 65.

In addition, Monsanto may not raise a successful implied preemption defense in this case. Even applying the *Wyeth* impossibility framework, EPA's actions related to glyphosate do not carry the force of law. First, as *Bates* makes clear, EPA's approval of a label in registration does not foreclose a claim that the pesticide label is nevertheless inadequate to protect public health and therefore constitutes misbranding. (*Bates*, *supra*, 544 U.S. at p. 447-48.) Second, a letter EPA sent to pesticide registrants on August 7, 2019, without any opportunity for notice and comment, and that that did not come out of any formal proceeding, lacks preemptive effect. Under *Wyeth* and its progeny, the EPA's actions related to glyphosate do not support a successful impossibility defense in this case.

BACKGROUND

Both California and the federal government have considered glyphosate and its associated health risks.

In California, glyphosate is listed as a chemical "known to cause cancer or reproductive toxicity." (Health & Saf. Code, § 25249.8, subd. (a); Lab. Code, § 6382.)[1] That listing is based on a determination by the

[1] The inclusion of a chemical on the Proposition 65 list does not automatically trigger a warning requirement. A business need not provide a (continued…)

International Agency for Research on Cancer (IARC), the cancer research arm of the United Nations World Health Organization, that glyphosate is an animal carcinogen and a probable human carcinogen. (*Monsanto Co. v. Office of Environmental Health Hazard Assessment* (2018) 22 Cal.App.5th 534, 542 [hereinafter "*Monsanto v. OEHHA*"].) IARC relied in part on evidence that there is a positive association in humans between exposure to glyphosate and non-Hodgkin's lymphoma.[2]

In April 2018, the Fifth District Court of Appeal rejected a constitutional challenge by Monsanto to the listing of glyphosate as a carcinogen under Proposition 65. (*Monsanto v. OEHHA*, *supra*, 22 Cal.App.5th at p. 560.) At the heart of the challenge was Monsanto's claim that IARC was an untrustworthy and unreliable foreign agency on whose determinations Proposition 65 could not constitutionally rely. The court rejected this contention, concluding that Proposition 65 reasonably relies on IARC to perform the statute's carcinogen identification function. (*Id.*)

EPA has reached a contrary determination about glyphosate, concluding that it is not likely to be carcinogenic to humans.[3] This was not

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(…continued)
warning for a listed chemical if it can show that the exposure it causes "poses no significant risk assuming lifetime exposure at the level in question." (Health & Saf. Code, § 25249.10, subd. (c).)

[2] "Some Organophosphate Insecticides and Herbicides," IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 12 (2017), [hereinafter "IARC Monograph"] available at https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Some-Organophosphate-Insecticides-And-Herbicides-2017, at p. 398 (last visited February 10, 2020).

[3] U.S. EPA: Glyphosate, Interim Registration Review Decision, Case No. 0178, Jan. 22, 2020, available at: https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf (last visited Feb. 11, 2020).

at all times the consensus view within the agency. Four scientists associated with EPA – the scientist from EPA's National Center for Computational Toxicology, who was a member of the IARC Working Group that determined that glyphosate was a likely human carcinogen,[4] and three members of the EPA Science Advisory Panel that reviewed glyphosate[5] – have agreed with IARC's finding that glyphosate is a probable human carcinogen.

In its amicus brief in *Hardeman*, EPA argues that although it has approved cancer warnings for glyphosate-based pesticides, its approval of the label for Roundup, which was the pesticide used by Mr. Johnson and which lacked a cancer warning, foreclosed any state-law claims "to the extent they are based on the lack of a warning on Roundup's labeling." (See Brief of the United States as Amicus Curiae in Support of Monsanto at pp. 13-14, 18-19 & fn. 14.) EPA's brief specifically references an informal letter that EPA sent to glyphosate registrants. (*Id.* at pp. 17-18 [citing EPA

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[4] IARC Monograph, *supra*, at pp. 3-7.

[5] Professor Luoping Zhang, who served on EPA's Food Quality Protection Act Science Review Board for the FIFRA Scientific Advisory Panel on Glyphosate, was the lead author on a meta-analysis published last year which concluded that glyphosate is a probable human carcinogen. Professors Elizabeth A. (Lianne) Sheppard and Emanuela Taioli, who also served on that Panel, were co-authors of that meta-analysis. (See FIFRA Scientific Advisory Panel Meeting Minutes and Final Report, No. 2017-01, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: EPA's Evaluation of the Carcinogenic Potential of Glyphosate*, December 13-16, 2016, available at https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf at pp.4-7 (last visited February 11, 2020) and Zhang, L., et al., *Exposure to glyphosate-based herbicides and risk for non-Hodgkin lymphoma: A meta-analysis and supporting evidence*, 781 Mutation Research/-Reviews in Mutation Research 186 (Feb. 5, 2019).) Dr. Zhang is currently a member of the California Office of Environmental Health Hazard Assessment's (OEHHA) Carcinogen Identification Committee.

Office of Chemical Safety & Pollution Prevention, Letter from Michael L. Goodis, Director Registration Division, Office of Pesticide Programs, to glyphosate registrants, Aug. 7. 2019, available at https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf (last visited February 11, 2020) (hereinafter the "Goodis Letter").) That letter, which was not issued as part of a formal proceeding or published in the Federal Register, but instead was announced in a press release, purported to inform registrants of EPA's determination that glyphosate is not carcinogenic, and stated that EPA would deem misbranded under FIFRA any products bearing a Proposition 65 warning statement due to the presence of glyphosate. (Goodis Letter at pp. 1-2.)

ARGUMENT

I. FIFRA DOES NOT EXPRESSLY PREEMPT STATE-LAW WARNING REQUIREMENTS EQUIVALENT TO FIFRA'S OWN REQUIREMENTS.

A. FIFRA does not preempt parallel state-law requirements.

FIFRA has long contemplated "the States' continuing role in pesticide regulation." (*Bates*, *supra*, 544 U.S. at p. 439.) It "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations. It does not, however, pre-empt any state rules that are fully consistent with federal requirements." (*Id.* at p. 454.) "To survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding FIFRA requirement . . . ." (*Id.* at p. 454; see also *Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.* (3d Cir. 2010) 617 F.3d 207, 222-23 [finding no preemption of state-law warning requirements that

did not "impose a duty inconsistent with or in addition to the text of the warning provisions of FIFRA's misbranding requirements"].)

A requirement under Proposition 65 or state common law that businesses provide a cancer warning for glyphosate-based pesticides is fully consistent with FIFRA's requirement that a pesticide not be misbranded. A product is misbranded under FIFRA if "the label does not contain a warning or caution statement which may be necessary . . . to protect health and the environment[.]" (7 U.S.C. § 136(q)(1)(G).) Proposition 65 requires a "clear and reasonable" warning that a chemical is "known to the state to cause cancer." (Health & Saf. Code, § 25249.6.)[6] Proposition 65, any other state-law remedies imposing similar warning requirements, and FIFRA thus impose parallel requirements. (See *Giglio v. Monsanto Co.* (S.D. Cal. Apr. 29. 2016) No. 15CV2279 BTM (NLS), 2016 WL 1722859, at *2 ["Here, Plaintiff essentially argues that Defendant failed to warn consumers that Roundup is carcinogenic. Failure to include a warning regarding known carcinogenic properties of a pesticide would

[6] The California Office of Health Hazard Assessment has adopted "safe harbor" warning methods and content deemed to meet this standard. (Cal. Code Regs., tit. 27, §§ 25601-25607.33.) Use of the safe-harbor warning language, however, is optional. A business may use any warning method that is clear and reasonable (Health & Saf. Code, § 25249.6; Cal. Code Regs., tit. 27, § 25600, subd. (f)), and the Attorney General and the courts have approved the use of nuanced warnings. (See, e.g., Consent Judgment between Plaintiffs People of the State of California and Andronico's Markets, Inc. in *Coordination Proceeding Proposition 65 Fish Cases*, Judicial Council Coordination Proceeding No. 4319 (Cal Super. Ct. 2004) [available at oag.ca.gov/sites/all/files/agweb/pdfs/prop65/andronicos.pdf, last visited, February 11, 2010]; see also *Ingredient Commc'n Council v. Lungren* (1992) 2 Cal.App.4th 1480, 1492 [whether a non-safe-harbor warning is clear and reasonable is determined on a case-by-case basis].)

constitute misbranding under [FIFRA].")[7] If a pesticide contains a chemical that has been determined to cause cancer – in this case, by a jury – then disclosure of that information is "necessary . . . to protect public health" under FIFRA and the failure to do so constitutes misbranding. (See *Bates*, *supra* 544 U.S. at p. 451 ["[state] remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA"].)

This is so even if EPA does not agree with the underlying factual determination that glyphosate is a carcinogen, because FIFRA does not give EPA sole authority to determine whether a pesticide is misbranded. As *Bates* demonstrates, this is an issue that states, and juries, may decide independent of EPA's determination that the warning is not needed under FIFRA. The Supreme Court has made clear that that the EPA does not have exclusive authority to enforce FIFRA's misbranding provision (*Bates*, *supra*, 544 U.S. at p. 451.)

In short, EPA lacks exclusive authority to determine which pesticides are carcinogenic, or to determine how best to protect public health, an area traditionally within the sphere of state regulation. As a result, so long as a state's warning requirement is equivalent to FIFRA's requirement to include information on a label necessary to protect public health and the environment, the state can continue to enforce it regardless of the EPA's own finding that glyphosate exposures do not pose a cancer risk. (See *Hernandez v. Monsanto Company*, (C.D. Cal. July 12, 2016) 2016 WL

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[7] Accord *Hardeman v. Monsanto (In re Roundup Prods. Liab. Litig.)* (N.D. Cal. July 12, 2019) MDL No. 2741, Case No. 16-md-02741, Dkt. No. 4565 at p. 2; *Pilliod v. Monsanto (In re Roundup Prods. Cases)*, (Alameda County Super. Ct. March 18, 2019) Case No. RG-17-862702, Order on Motion for Summary Judgment at pp. 17-18; 4 Appellant's Appendix (hereinafter "AA") 3170 at pp. 3207-3211, Order on Monsanto's Motion for Summary Judgment at pp. 38-42.

6822311 at *8 ["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"].)

B. Proposition 65 permits warnings outside the scope of FIFRA's preemption provision.

There is an additional reason why FIFRA's express preemption provision does not reach Proposition 65 warnings in particular. Even if Proposition 65 were construed not to impose a warning parallel to what FIFRA requires, businesses can comply with Proposition 65 with a point-of-sale warning that does not appear on a pesticide's labeling or packaging. (*Chem. Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 945-47.)

FIFRA's preemption provision is narrow and does not apply to warnings that are not affixed to a pesticide's packaging. FIFRA's preemption provision provides that a state may not impose any requirement for "labeling or packaging" in addition to or different from FIFRA's own requirements. (7 U.S.C. § 136v, subd. (b).) FIFRA defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." (7 U.S.C. § 136, subd. (p)(1).) "Labeling" means "all labels and all other written, printed, or graphic matter – (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device . . . . " (7 U.S.C. § 136, subd. (p)(2).)

Proposition 65 does not mandate a warning on a product's packaging, but instead may be satisfied through point-of-sale warnings such as through a posted sign, a shelf sign or a shelf tag. (Cal. Code Regs., tit. 27, § 25602.1, subd. (a)(1).). There can be no dispute that signs and shelf tags are not "labels," as they are not "on, or attached to, the pesticide or device

or any of its containers or wrappers." The only question is whether they may be constitute "labeling" under FIFRA. The answer is no.

The Ninth Circuit has considered and decided this precise issue. In *Chemical Specialties*, the court held that shelf signs providing a Proposition 65 warning were not preempted by FIFRA. (*Chemical Specialties*, *supra* 958 F.2d at p. 946.) The court explained that under FIFRA, "labeling" is limited to writing "attached to the immediate container of the product in such a way that it can be expected to remain affixed during the period of use." (*Ibid.*, internal quotation marks and citation omitted). If it were otherwise, the court reasoned, then price stickers, flyers indicating that a product is on sale, and "even the logo on exterminator's hat" would all constitute impermissible labeling. (*Ibid.*)[8]

Other federal appellate courts have similarly applied a narrow definition of "labeling" for purposes of FIFRA preemption. In *New York State Pesticide Coalition, Inc. v. Jorling*, the Second Circuit upheld a New York law, which required notice to the public about the use of poisonous chemicals, against a FIFRA preemption challenge. ((2d Cir. 1989) 874 F.2d 115, 116.) The court explained that "FIFRA 'labeling' is designed to be read and followed by the end user," and that notification requirements "do not impair the integrity of the FIFRA label." (*Ibid.*) Similarly, the Third Circuit concluded that a marketing brochure was not "labeling" under FIFRA because it contained no instructions for the use of the product.

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[8] See also *D-Con Co. Inc. v. Allenby* (N.D. Cal. 1989) 728 F.Supp. 605, 607 ["[m]any warning methods, including the point-of-sale signs currently designated a 'safe harbor' under Prop 65, may satisfy the requirements of the state of California without infringing on federal supremacy in the area of pesticide labeling"]; *People v. Cotter* (1997) 53 Cal.App.4th 1373, 1380, 1390-92 [assertion that point-of-sale signs were "labels" under the Federal Hazardous Substances Act was "plainly erroneous"].)

(*Indian Brand Farms, supra*, 617 F.3d at pp. 217-18 [noting also that it was necessary to limit the scope of "labeling" in order to meet Congress's "narrow[] objective"].)[9]

FIFRA's express preemption provision narrowly applies to labeling and packaging. Even if FIFRA might bar a Proposition 65 warning from a pesticide's packaging, point-of-sale warnings are not preempted.

II. NEITHER THE EPA'S APPROVAL OF ROUNDUP'S LABEL NOR THE GOODIS LETTER TO GLYPHOSATE REGISTRANTS IMPLIEDLY PREEMPTS PARALLEL STATE-LAW WARNING REQUIREMENTS LIKE THOSE OF PROPOSITION 65.

State law is impliedly preempted where it is "impossible for a private party to comply with both state and federal requirements." (*English v. General Elec. Co.* (1990) 496 U.S. 72, 79). It is difficult for a defendant to meet this standard because "[i]mpossibility pre-emption is a demanding defense." (*Wyeth*, *supra*, 555 U.S. at p. 573). The "possibility of impossibility is not enough." (*Merck Sharp & Dohme Corp. v. Albrecht* (2019) 139 S.Ct. 1668, 1678, internal quotation marks and citations omitted.) Consequently, the Supreme Court has refused to find such impossibility "where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit." (*Id.*, internal quotation marks and citations omitted.) In addition, where, as in FIFRA,

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[9] In the context of considering preemption under a different statute, the Federal Meat Inspection Act ("FMIA"), the Fourth District Court of Appeal stated that it did not find the Ninth Circuit's reasoning in *Chemical Specialties* persuasive, and held that a shelf sign was "labeling." (*American Meat Institute v. Leeman* (2010) 180 Cal.App.4th 728, 758.) Nevertheless, *Leeman* is not binding on this Court, and it expressly distinguished *Chemical Specialties* on the ground that it concerned FIFRA rather than the FMIA. (*Leeman*, *supra*, 180 Cal.App.4th at p. 758 ["Whatever value there may be under FIFRA to focus, during a preemption analysis, on whether the material accompanies the pesticide *during use*, we see no basis for importing that focus into the FMIA."] [emphasis in original].)

"Congress establishes a regime of dual state-federal regulation, conflict-pre-emption analysis must be applied sensitively . . . so as to prevent the diminution of the role Congress reserved to the States while at the same time preserving the federal role." (*Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 942, internal quotation marks and citations omitted.)

A. Preemption of long-standing state health and safety laws is disfavored.

Implied preemption analysis proceeds from the premise that "the historic police powers of the States [are] not to be superseded by . . . [a] Federal Act unless that [is] the clear and manifest purpose of Congress." (*Cipollone v. Liggett Group* (1992) 505 U.S. 504, 516, brackets and ellipsis in original, internal citation omitted.) Courts must construe federal statutes "in light of the presumption against the pre-emption of state police power regulations." (*Id.* at p. 518.) The Supreme Court has likewise concluded that the scope of preemption must be narrowly construed, rejecting any suggestion that the presumption "should apply only to the question whether Congress intended any pre-emption at all, as opposed to questions concerning the *scope* of [preemption]. . . ." (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 485, emphasis in original.)

The presumption against preemption is especially strong when applied to state health and safety regulations. "[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern." (*Hillsborough County v. Automated Med. Labs., Inc.* (1985) 471 U.S. 707, 719.) And as the Supreme Court noted in declining to find FIFRA preemption in *Bates*, "[t]he long history of tort litigation against manufacturers of poisonous substances adds force" to the presumption against preemption. (*Bates*, *supra*, 544 U.S. at p. 450 ["[i]f Congress had

intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly"].)

The California Supreme Court has confirmed that "this venerable presumption . . . provides assurance that the federal-state balance . . . will not be disturbed unintentionally by Congress or unnecessarily by the courts." (*Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 957, ellipsis in original, internal quotation marks and citation omitted.)

California's health and safety laws like Proposition 65 lie at the heart of the State's traditional police powers. (See *Cong. of Calif. Seniors v. Catholic Healthcare W.* (2001) 87 Cal.App.4th 491, 496 ["[t]he fact that public health is a field historically within the police powers of the states means that the party asserting preemption must establish that preemption was the clear and manifest purpose of Congress"], internal quotation and citation omitted.) As described below, a proper construction of the preemptive reach of FIFRA demonstrates that FIFRA and Proposition 65 and similar state-law requirements may coexist harmoniously.

B. EPA's approval of Roundup's label does not have preemptive effect.

The Supreme Court's decision in *Bates* established that EPA's approval of a pesticide's label does not shield the manufacturer from liability under FIFRA or state law consistent with FIFRA. In *Bates*, a plaintiff alleged state-law failure-to-warn claims based on a pesticide label that had been approved by the EPA in the course of registration. (*Supra,* 544 U.S. at p. 434-435.) The Court allowed the plaintiff's claims to go forward notwithstanding EPA's approval of the label at issue. (*Id.* at pp. 452-53.) Thus, "mere inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration [does] not necessarily mean that the state law duty [is] preempted." (*Indian Brand Farms, Inc., supra*, 617 F.3d at p. 222).

Indeed, as the trial court in this case found, and numerous other courts have agreed, this result is compelled by the text of the statute. (See, e.g., 4 AA at 3210-11.) Pursuant to 7 U.S.C. § 136a, subdivision (f)(2), EPA's approval of a pesticide merely constitutes prima facie evidence that the pesticide and its label comply with FIFRA. Prima facie evidence, however, "is not conclusive proof," and "'[i]n no event shall registration of an article be construed as a defense for the commission of any offense under FIFRA.'" (*Hardeman v. Monsanto*, (N.D.Cal. 2016) 216 F.Supp.3d 1037, 1038 [quoting 7 U.S.C. § 136, subd. (f)(2)], appeal pending (9th Cir.) Case Nos. 19-16636 and 19-16708].) Congress did not authorize EPA to foreclose claims that a label fails to adequately protect public health.

Moreover, to the extent the EPA contends in its brief that its decision *not* to require a cancer warning is evidence of a federal policy against such warnings, the law is clear that this kind of "preemption by nonregulation" would require an affirmative decision not to regulate that is the functional equivalent of a regulation. (See *Sprietsma v. Mercury Marine* (2002) 537 U.S. 51, 65; *cf. Geier v. American Honda Motor Co.* (2000) 529 U.S. 861, 881 [adoption by the Department of Transportation of motor vehicle standards that allowed automobile manufacturers to install alternative protection systems in their fleets represented an affirmative policy decision to allow the alternative systems].) There must be an "authoritative message of a federal policy against state regulation." (*Viva! Int'l*, *supra*, 41 Cal.4th at p. 946, internal quotation marks and citation omitted.) Approval of a pesticide label without a warning – particularly where there is no evidence that the agency even considered whether to require the cancer warning when it approved the label – does not amount to a federal policy with the power to preempt.

C. The Goodis Letter does not carry the force of law.

Nor does the Goodis Letter to glyphosate registrants support preemption of claim under Proposition 65 or any related state law.

While agency actions can have preemptive effect under certain circumstances, "the only agency actions that can determine the answer to the pre-emption question, of course, are agency actions taken pursuant to the [agency's] congressionally delegated authority." (*Merck*, *supra*, 139 S.Ct. at p. 1679; cf. *Wyeth*, *supra*, 555 U.S. at pp. 575-80 [opinion expressed in preamble to FDA regulation governing content and format of prescription drug labels that state law frustrates the agency's implementation of its statutory mandate did not bear the force of law, and did not have preemptive effect].) "Pre-emption takes place only when and if the agency is acting within the scope of its congressionally delegated authority, for an agency literally has no power to act, let alone pre-empt [the laws of] a sovereign State, unless and until Congress confers power upon it." (*Merck*, *supra*, 139 S.Ct. at p. 1679 [internal quotation and citation omitted].)

The Goodis Letter states, without reference to any specific warning statement proposed or approved:

> Given EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,' EPA considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement. As such, pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded pursuant to section 2(q)(1)(A) of FIFRA and as such do not meet the requirements of FIFRA . . . . EPA will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products. The warning statement must also be removed from all product labels where the only basis for the warning is glyphosate, and from any materials considered labeling under FIFRA for those products.

(Goodis Letter at pp. 1-2.) It is beyond the scope of this brief to challenge the substance of the Goodis Letter, other than to note that it does not reflect an accurate understanding of what type of language could be included in a Proposition 65 warning to ensure that it is both factual and not misleading. The issue for this Court is whether the Goodis Letter could possibly have any preemptive effect. The Goodis Letter is not formal agency action and therefore lacks the force of law and has no preemptive effect.

The Goodis Letter cannot preempt potential Proposition 65 claims because it does not represent formal, final agency action. Because the Supremacy Clause "privileges only [l]aws of the United States, an agency pronouncement must have the force and effect of federal law to have preemptive force." (*Reid v. Johnson & Johnson* (9th Cir. 2015) 780 F.3d 952, 964, citations and internal quotation marks omitted; cf., e.g., *Sierra Pacific Holdings, Inc. v. County of Ventura* (2012) 204 Cal.App.4th 509, 518 [advisory guidelines "are not regulations and do not have the force and effect of law," and thus cannot preempt].) Conflict preemption is created by federal law – federal statutes, regulations, and final and formal agency actions. Thus, a federal statute or regulation that is properly adopted in accordance with statutory authorization may have preemptive power. (See *City of New York v. FCC* (1988) 486 U.S. 57, 63.) And in limited circumstances, "a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation." (*Id.* at pp. 63-64.)

But "federal law capable of preempting state law is [not] created every time someone acting on behalf of an agency makes a statement[,]" (*Fellner v. Tri-Union Seafoods, LLC* (3d Cir. 2008) 539 F.3d 237, 245), and a legal opinion expressed in an informal letter does not have preemptive effect. (See, e.g., *Wabash Valley Power Ass'n Inc. v. Rural Electrification Admin.* (7th Cir. 1990) 903 F.2d 445, 454 [regulatory letter from agency not

sufficient to preempt state law].) The Goodis Letter was neither adopted as a regulation nor issued pursuant to any regulation. There is no indication that Congress intended this type of agency pronouncement "to carry the binding and exclusive force of federal law." (*Reid*, *supra*, 780 F.3d at p. 964.)

Indeed, a number of courts have specifically held that informal federal agency actions lack the force to preempt state regulation. (See *Reid*, *supra*, 780 F.3d 952 (FDA letter discussing agency enforcement intentions regarding certain health claims, and finding company statements complied with FDA regulations, did not have preemptive effect); *Fellner*, *supra*, 539 F.3d at p. 245 [informal FDA letter did not preempt state-law duty to warn of risks of fish consumption] ["Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force"]; *Wabash Valley Power Ass'n*, *supra*, 903 F.2d at p. 454 [agency letter stating policy position and conclusions on preemption, but not observing any formal rulemaking procedures, did not preempt state law] ["[w]e have not found any case holding that a federal agency may preempt state law without either rulemaking or adjudication"]; *United States v. Ferrara* (D.D.C. 1993) 847 F.Supp. 964, 969 [for purposes of preemption, policy memorandum is not the "equivalent of 'federal law'"].)

Dowhal v. SmithKline Beecham Consumer Healthcare (2004) 32 Cal.4th 910 does not compel a contrary conclusion. In *Dowhal* the California Supreme Court held that a Proposition 65 warning on nicotine patches – stating that nicotine is known to cause birth defects – would conflict with a federal policy to encourage smokers to quit smoking by using nicotine patches and similar products. (See *Dowhal*, *supra*, 32 Cal.4th at pp. 934-35.) In so holding, the Court emphasized a letter from

the FDA denying a citizen petition to require Proposition 65 warnings on nicotine replacement therapy products. (See *Dowhal*, *supra*, 32 Cal.4th at pp. 922, 929.) Unlike the Goodis Letter in this case, however, the FDA's denial of the citizen petition in *Dowhal* was a formal agency determination. Under the FDA's regulations, a citizen petition initiates a formal proceeding to obtain a final agency determination. (21 C.F.R. § 10.25, subd. (a).) Other interested persons may participate in the proceedings, which allows the agency to consider different views before ruling. (21 C.F.R. § 10.30, subd. (d).)

In determining that the agency's response to the citizen petition had preemptive effect, the *Dowhal* Court noted that, although the FDA previously had sent companies letters ordering them not to place warnings on their packaging (32 Cal.4th at p. 920), there was no final action until the agency provided a formal response to the citizen petition. (See *id.* at p. 927.) In fact, in *Dowhal*, the FDA acknowledged that the ruling on the citizen petition was the agency's "first definitive ruling on the subject[,]" and the letters it previously had sent to nicotine device manufacturers did not represent "definitive advice" from the agency. (*Dowhal*, *supra*, 32 Cal.4th at p. 927.)

The relevant statutory structure provides for a number of formal agency proceedings that do not appear to have taken place in connection with the issuance of the Goodis Letter. Under FIFRA, a pesticide manufacturer may seek EPA approval to change its label. (7 U.S.C. § 136a, subd. (f)(1).) FIFRA also provides for cancellation proceedings, pursuant to which a hearing may be held to determine whether a pesticide's labeling fails to comply with the statute's provisions (7 U.S.C. § 136d, subd. (b)); and EPA may "take other enforcement action if it determines that a registered pesticide is misbranded." (*Bates*, *supra*, 544 U.S. at p. 439.) The FIFRA regulations provide their own procedures: EPA may "evaluate

a pesticide use," either on its own or at the suggestion of an "interested person," (40 C.F.R. § 154.10), and EPA may conduct a "Special Review" of a pesticide use under certain circumstances, (40 C.F.R. § 154.7). The statute provides for judicial review of such orders and final agency actions in federal court. (7 U.S.C. § 136n.) If there had been a formal proceeding, and EPA had, for example, denied a request to amend a label under 7 U.S.C. §136a, subdivision (f)(1)), a reviewing court could have determined whether compliance with both state and federal law was truly impossible, a showing that has not been made here. (See *Merck*, *supra*, 139 S.Ct. at p. 1678, citation and internal quotation marks omitted ["possibility of impossibility [is] not enough"].)

There is no evidence that the Goodis Letter was issued pursuant to any of these formal statutory or administrative procedures. As a result, it does not have preemptive effect. (See *Fellner*, *supra*, 539 F.3d at 245 ["[w]e decline to afford preemptive effect to less formal measures lacking the 'fairness and deliberation' which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law"].) Under *Wyeth* and *Merck*, Monsanto therefore may not rely on the Goodis Letter to argue that it was impossible to comply with both federal and state law. (*Wyeth*, *supra*, 555 U.S. at pp. 575-80; *Merck*, *supra*, 139 S.Ct. at p. 1679.)

CONCLUSION

This Court should conclude that neither FIFRA nor EPA's actions related to glyphosate preempt state-law warning requirements.

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CERTIFICATE OF COMPLIANCE

I certify that the attached Brief of the California Attorney General as Amicus Curiae In Support of Plaintiff uses a 13 point Times New Roman font and contains 5422 words.

Dated: February 11, 2020

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