IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

EDWIN HARDEMAN, Plaintiff-Appellee/Cross-Appellant, **v.** **MONSANTO COMPANY,** Defendant-Appellant/Cross-Appellee.	Case Nos. 19-16636, 19-16708

On Appeal from the United States District Court for the Northern District of California,

Case Nos. 16-cv-00525 & 16-md-02741
(Chhabria, J.)

AMICUS CURIAE BRIEF OF THE STATE OF CALIFORNIA 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*, 544 U.S. 431, 450 (2005).

The United States Environmental Protection Agency ("EPA") has filed a brief as amicus curiae, which argues that FIFRA preempts claims under state law for failure to warn. The brief emphasizes the EPA's approval of a label for a glyphosate-based pesticide containing no cancer warning and highlights an EPA official's subsequent letter to pesticide registrants stating EPA's view that labels bearing a glyphosate cancer warning under California's Safe Drinking Water and Toxic Enforcement Act ("Proposition 65") would be "misbranded" under FIFRA. Despite the fact that Mr. Hardeman 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 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 or 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. *Chem. Specialties Mfrs. Ass'n, Inc. v. Allenby*, 958 F.2d 941, 945-47 (9th Cir. 1992).

In addition, Monsanto may not raise a successful implied preemption defense in this case. Even applying the impossibility framework set forth in *Wyeth v. Levine*, 555 U.S. 555 (2009), EPA's actions related to glyphosate do not carry the force of law. First, 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*, 544 U.S. at 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.

This amicus curiae brief is submitted by the State of California, by and through the Attorney General. The Attorney General is the chief law officer of the State with statutory responsibility for enforcing Proposition 65. The Attorney General submits this amicus brief because the outcome of this case could affect the State's ability to protect public health. In particular, while this case involves

claims under state common law, the Court's resolution of the preemption questions before it could impact the State's authority to enforce Proposition 65. Proposition 65 provides an important tool for the State to protect public health, and the State has a special interest in demonstrating why state-law remedies like Proposition 65 and other state health and safety laws are not preempted by federal law.

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." Cal. Health & Saf. Code § 25249.8(a); Cal. Lab. Code § 6382.[1] That listing is based on a determination by the 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*, 22 Cal.App. 5th 534, 542 (Cal.Ct.App 2018) (hereinafter "*Monsanto*

[1] The inclusion of a chemical on the Proposition 65 list does not automatically trigger a warning requirement. A business need not provide a 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." Cal. Health & Saf. Code § 25249.10(c).

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 California Court of Appeal upheld the listing of glyphosate as a carcinogen under Proposition 65. *Monsanto v. OEHHA*, 22 Cal.App.5th at 560. At the heart of Monsanto's challenge to this listing was its 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 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

[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 398 (last visited March 18, 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 March 18, 2020).

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, EPA argues that although it has approved cancer warnings for other glyphosate-based pesticides, its approval of the label for Roundup, which was the pesticide used by Mr. Hardeman and which lacked a cancer warning, forecloses 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 13-14, 18-19 & n. 14. EPA's brief specifically references an informal letter that EPA sent to glyphosate registrants after the jury verdict against Monsanto in this and two other cases. *Id.* at 17-18 (citing EPA Office of Chemical Safety & Pollution Prevention, Letter from Michael L. Goodis,

[4] IARC Monograph, at 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 4-7 (last visited March 18, 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 Carcinogen Identification Committee.

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 March 18, 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 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*, 544 U.S. at 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 454. "To survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding FIFRA requirement . . . ." *Id.* at 454; *see also Indian*

Brand Farms, Inc. v. Novartis Crop Protection Inc., 617 F.3d 207, 222-23 (3d Cir. 2010) (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." Cal. 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.*

[6] The California Office of Environmental 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, Cal. Health & Saf. Code § 25249.6; Cal. Code Regs. tit. 27, § 25600(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, March 18, 2020); *see also Ingredient Commc'n Council v. Lungren* 2 Cal. App. 4th 1480, 1492 (1992) (whether a non-safe-harbor warning is clear and reasonable is determined on a case-by-case basis).

Monsanto Co., No. 15CV2279 BTM (NLS), 2016 WL 1722859, at *2 (S.D. Cal. Apr. 29. 2016), ("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 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*, 544 U.S. at 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 the EPA does not have exclusive authority to enforce FIFRA's misbranding provision. *Bates*, 544 U.S. at 451 ("Private remedies that

[7] *Accord Hardeman v. Monsanto (In re Roundup Prods. Liab. Litig.)* MDL No. 2741, Case No. 16-md-02741, Dkt. No. 4565 at 2 (N.D. Cal. July 12, 2019); *Pilliod v. Monsanto (In re Roundup Prods. Cases)*, Case No. RG-17-862702, Order on Motion for Summary Judgment at 17-18 (Alameda County Super. Ct. March 18, 2019).

enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA").

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*, 2016 WL 6822311 at *8 (C.D. Cal. July 12, 2016) ("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*, 958 F.2d at 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(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(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(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(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 constitute "labeling" under FIFRA. The answer is no.

This Court has considered and decided this precise issue. In *Chemical Specialties*, this Court held that shelf signs providing a Proposition 65 warning were not preempted by FIFRA. *Chemical Specialties*, 958 F.2d at 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." *Id.*, 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. *Id.*[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. 874 F.2d 115, 116 (2d Cir. 1989). 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." *Id*. 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. *Indian Brand Farms*, 617 F.3d at 217-18 (noting also that it was

[8] *See also D-Con Co. Inc. v. Allenby*, 728 F. Supp. 605, 607 (N.D. Cal. 1989) ("[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* 53 Cal. App. 4th 1373, 1380, 1390-92 (Cal.Ct.App. 1997) (assertion that point-of-sale signs were "labels" under the Federal Hazardous Substances Act was "plainly erroneous").

necessary to limit the scope of "labeling" in order to meet Congress's "narrow[] objective").

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 because in a particular case it did not parallel FIFRA, 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.*, 496 U.S. 72, 79 (1990). It is difficult for a defendant to meet this standard because "[i]mpossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. The "possibility of impossibility is not enough." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019), 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, 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." *Northwest Cent. Pipeline v. Kan. Corp. Comm'n*, 489 U.S. 493, 515 (1989).

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, 505 U.S. 504, 516 (1992), 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 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*, 518 U.S. 470, 485 (1996), 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.*, 471 U.S. 707, 719 (1985). 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*, 544 U.S. at 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 Supreme Court has confirmed that "this presumption . . . provides assurance that the federal-state balance . . . will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977), internal quotation marks 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* establishes that EPA's approval of a company's proposed pesticide 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. 544 U.S. at 434-435. The Court allowed the plaintiff's claims to go forward notwithstanding EPA's approval of the label at issue. *Id.* at 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.*, 617 F.3d at 222.

Indeed, as the district court in this case concluded, this result is compelled by the text of FIFRA. Pursuant to 7 U.S.C. § 136a(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*, 216 F. Supp. 3d 1037, 1038 (N.D.Cal. 2016) (quoting 7 U.S.C. § 136(f)(2)). 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 implied 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*, 537 U.S. 51, 65 (2002); *cf. Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (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). Approval of a

pesticide label without a warning – particularly where there is no evidence that the agency even considered whether to require a 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, contrary to EPA's contention, does the Goodis Letter to glyphosate registrants support preemption of a claim under Proposition 65 or any related state law. *See* Brief of the United States as Amicus Curiae in Support of Monsanto at 18.

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*, 139 S. Ct. at 1679; cf. *Wyeth*, 555 U.S. at 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*, 139 S. Ct. at 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 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 the 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 has any preemptive effect. The Goodis Letter is not formal agency action, and therefore lacks the force of law and has no preemptive effect.

Just as the Goodis letter cannot preempt the common law claim in this case, it 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*, 780 F.3d 952, 964 (9th Cir. 2015), citations and internal quotation marks omitted.

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*, 486 U.S. 57, 63 (1988). And in limited circumstances, "a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation." *Id*. at 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*, 539 F.3d 237, 245 (3d Cir. 2008), 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.* 903 F.2d 445, 454 (7th Cir. 1990) (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 informal agency statement "to carry the binding and exclusive force of federal law." *See Reid*, 780 F.3d at 964.

Indeed, a number of courts have specifically held that informal federal agency actions lack the force to preempt state regulation. *See Reid*, 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*, 539 F.3d at 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*, 903 F.2d at 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*, 847 F. Supp. 964, 969 (D.D.C. 1993) (for purposes of preemption, policy memorandum is not the "equivalent of 'federal law'").[9]

In this case, 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(f)(1). FIFRA also provides for cancellation proceedings, pursuant to which a hearing may be held to determine

[9] *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (Cal. 2004), does not suggest a contrary conclusion. In *Dowhal*, the California Supreme Court held that a Proposition 65 warning on nicotine patches would conflict with a federal policy to encourage smokers to quit smoking by using nicotine patches. 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 id.* at 922, 929. But unlike the Goodis Letter in this case, the FDA's denial of the citizen petition in *Dowhal* was a formal agency determination. *Id.* at 927.

whether a pesticide's labeling fails to comply with the statute's provisions, 7 U.S.C. § 136d(b); and EPA may "take other enforcement action if it determines that a registered pesticide is misbranded." *Bates* 544 U.S. at 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(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* 139 S. Ct. at 1678 ("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*, 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*, 555 U.S. at 575-80; *Merck*, 139 S. Ct. at 1679.

CONCLUSION

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

Dated: March 23, 2020

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

9th Cir. Case Number(s) 19-16636, 19-16708

I am the attorney or self-represented party.

This brief contains 4945 words, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief *(select only one)*:

[ ] complies with the word limit of Cir. R. 32-1.

[ ] is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.

[**X**] is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).

[ ] is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.

[ ] complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one)*:
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Signature s/ Andrew Wiener **Date** March 23, 2020

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 15. Certificate of Service for Electronic Filing

9th Cir. Case Number(s) 19-16636, 19-16708

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Amicus Curiae Brief of the State of California

Signature s/ Andrew Wiener **Date** March 23, 2020