STEPTOE LLP
Melanie A. Ayerh, SBN 303211
mayerh@steptoe.com
633 West Fifth Street, Suite 1900
Los Angeles, California 90071
Telephone: (213) 439-9432
Facsimile: (213) 439-9599

STEPTOE LLP
Shannen W. Coffin, DC Bar #449197
Michael Boucher, DC Bar #453008
Pro Hac Vice Anticipated
scoffin@steptoe.com
mboucher@steptoe.com
1330 Connecticut Ave., N.W.
Washington, D.C. 20036
Telephone: (202) 429-3000
Facsimile: (202) 429-3902

Counsel for Amicus Curiae CropLife America

STEPTOE LLP
Anthony Hopp, Illinois SBN: 6199290
Christopher L. Yeatman. Illinois SBN: 6342980
Pro Hac Vice Anticipated
ahopp@steptoe.com
cyeatman@steptoe.com
227 West Monroe St., Suite 4700
Chicago, Illinois 60606
Telephone: (312) 577-1300
Facsimile: (312) 577-1370

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION

This document relates to:

All Category One cases

Case No.: 3:16-md-02741-vc

MDL No. 2741

CROPLIFE AMERICA'S BRIEF OF AMICUS CURIAE IN SUPPORT OF DEFEFNDANT'S MOTIONS FOR SUMMARY JUDGMENT

Hearing Date: November 16, 2026
Time: 1:00 p.m. PT
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INTEREST OF AMICUS CURIAE

CropLife America respectfully files brief *amicus curiae* in response to this Court's invitation for briefing addressing the scope of federal preemption on various state tort claims. *See* Dkt. 22732. Established in 1933, CropLife America is the national trade association for the pesticide industry, representing developers, manufacturers, formulators, and distributors of pesticides and plant science solutions. CropLife America's member companies produce, sell, and distribute pesticides, including herbicides, insecticides, and fungicides, which American farmers use to provide consumers with abundant food, fuel, and fiber. CropLife America is committed to safe and responsible use of the industry's products.[1]

CropLife America submits that this Court will benefit from its members' substantial experience in the realm of federal and state pesticide regulation and their understanding of Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which broadly preempts state laws that prescribe requirements different from or in addition to federal labeling and packaging requirements. *See* 7 U.S.C. § 136v(b). EPA's review process has resulted in repeated determinations that glyphosate-based pesticides are unlikely to cause cancer and that a cancer warning should not be included on the product labels. EPA's labeling determination, made as part of pesticide registration and registration review, controls and preempts the various tort claims with respect to which this Court has sought *amicus* briefing.

SUMMARY OF ARGUMENT

FIFRA preempts any state law requirements that seek to vary pesticides' EPA-approved labeling or formulation, especially when, as is the case for the glyphosate-based products at issue in this proceeding, EPA has carefully reviewed the science and determined that the products "when used in accordance with widespread and commonly recognized practice [] will not generally cause unreasonable adverse effects on the environment," including "any unreasonable

[1] No counsel for any party authored this brief in whole or in part, nor did such counsel, any party, or other person other than amicus curiae, its members, and its counsel make monetary contributions intended to fund the brief's preparation. Monsanto Company's ("Monsanto") parent company, Bayer Corp., is a member of CropLife America and pays member dues but did not contribute any money specifically intended to fund preparation or submission of this brief.

risk to man[.]" 7 U.S.C. § 136a(c)(5)(D); 7 U.S.C. § 136(bb). In *Monsanto Co. v. Durnell*, the Supreme Court held that a lay jury cannot subject a registrant to tort liability under state law for not including a health and safety warning on its label where, as here, EPA has affirmatively declined to include the warning as part of its federal regulation of that pesticide label. 609 U.S. 371 (2026).

Durnell's reasoning applies more broadly, however, to preclude state tort claims that would functionally require manufacturers to change the formulation of a registered and EPA-approved product and/or restrict product-related statements that are consistent with the EPA-approved labeling. *Durnell* confirms that FIFRA preemption extends to *any state-law claim* seeking to impose a duty on the pesticide manufacturer that would require it to depart from EPA-approved labeling. As applied here, Plaintiffs' negligence, design defect, and warranty claims therefore are expressly preempted to the extent they rest on Monsanto's alleged failure to provide a cancer warning. That conclusion applies to all FIFRA "labeling," not merely the physical label attached to a pesticide container. Plaintiffs cannot evade preemption by demanding the same cancer warning in accompanying or referenced materials. Nor may they recast that theory as a challenge to advertising or promotional statements where the demanded statements would conflict with claims EPA approved in connection with a pesticide's registration.

The preemption hurdles faced by the MDL Plaintiffs go well beyond the express preemption issue explicitly decided in *Durnell*. To the extent Plaintiffs' claims challenge Roundup®'s formulation, those claims are also *impliedly* preempted. A state-law duty requiring Monsanto to alter Roundup®'s EPA-approved formulation would obstruct FIFRA's uniform regulatory framework and conflict with a pesticide manufacturers' obligations under FIFRA, effectively compelling Monsanto to withdraw the product from the market to avoid state tort liability—as it has already done with consumer applications. But state law liability cannot flow from a pesticide manufacturer's *compliance* with EPA's decisions to grant a pesticide registration and the pesticide label that accompanies it.

Allowing juries to override EPA's expert determinations would expose manufacturers to massive liability for complying with federal requirements, threaten beneficial pesticide uses, and

replace nationwide uniformity with conflicting state mandates. FIFRA's preemption clause expressly preempts "any state tort claim" that would require a pesticide manufacturer to use labeling different from or in addition to the EPA-approved labeling. *Durnell*, 609 U.S. at 390-91. The various state tort claims advanced by the Plaintiffs here—specifically, their negligence, design defect, and breach of express and implied warranty claims—seek that outcome. The Court should grant Monsanto summary judgment on all such claims.

BACKGROUND

I. FIFRA Overview

State law is expressly preempted when Congress "has prohibited state regulation of the particular aspects of commerce involved in this case." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). FIFRA, the "comprehensive regulatory statute" governing the sale, use, and labeling of "pesticides," *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 987, 991 (1984), does just that. Congress included a "Uniformity" provision in the statute, expressly providing that a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" the statute. 7 U.S.C. § 136v(b). This express preemption provision protects "EPA's comprehensive and exclusive authority in registering pesticides and approving labels." *Durnell*, 609 U.S. at 380.

FIFRA prohibits the sale of "any pesticide that is not registered." 7 U.S.C. § 136a(a).[2] EPA "shall register a pesticide" *only* if it determines that, "when considered with any restrictions imposed," the pesticide meets four general requirements: 1) its composition is such as to warrant the proposed claims for it; 2) its labeling complies with FIFRA's requirements; 3) it will perform its intended function without unreasonable adverse effects on the environment; and 4) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(5).

[2] FIFRA defines "pesticide" to include "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest" (7 U.S.C. § 136(u)) and encompasses glyphosate-based herbicides. *See* 40 C.F.R. § 152.5(c) (defining "pest" to include "any plant growing where not wanted").

FIFRA defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment," a calculus that requires EPA to balance the "economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb). It also includes consideration of any "human dietary risk from residues that result from a use of a pesticide" on food inconsistent with Federal Food, Drug, and Cosmetic Act safety standards. *Id.*

After a pesticide is registered, FIFRA requires EPA to conduct a registration review every 15 years to determine whether the pesticide continues to satisfy registration standards. *See* 7 U.S.C. § 136a(g); 40 C.F.R. §§ 155.40-155.58. This process involves an up-to-date review of the relevant science under notice-and-comment procedures. *See* 40 C.F.R. §§ 155.50(b), (c); *see also* 40 C.F.R. § 155.58(b)(4) (requiring EPA to specify proposed labeling changes as part of registration review).

The label attached to a pesticide product, other written, printed, or graphic matter accompanying the product, and materials referenced on the label or in accompanying literature—all of which can qualify as "labeling"—are a central focus of EPA's registration and registration review processes.[3] FIFRA and its implementing regulations require EPA to review and approve the pesticide label, including necessary human health and safety warnings, and generally prohibit any change to that label without EPA approval. *See Durnell*, 609 U.S. at 377-78, 390-91. Once approved by EPA, the "label is the law."[4]

EPA reviews a pesticide label to ensure that, among other things, it contains warnings and cautionary statements "adequate to protect health and the environment," and that the overall

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[3] Though the terms are closely related, FIFRA separately defines the "label" and "labeling." "The term 'label' means 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). A pesticide label is a subset of the overall product "labeling": "The term '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, except to certain official publications. *Id.* at § 136(p)(2).

[4] U.S. Environmental Protection Agency, "Introduction to Pesticide Labels" (April 2025), https://tinyurl.com/5n8kdeh2.

labeling does not contain any "statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading." 7 U.S.C. §§ 136(q)(1)(A), (G). For example, if a label refers to a manual on how to apply the pesticide, that manual is also labeling that the user must follow and EPA must approve.[5]

"Pesticide product labels provide critical information about how to safely and legally handle and apply pesticides." EPA, Office of Pesticide Programs, Label Review Manual 1-2.[6] A "critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used." *Id.* The accuracy of the label is "vital" to EPA's (and other governmental agencies') management and mitigation of pesticide risks; to these agencies' enforcement of pesticide production, distribution, sale, and use requirements; to registrants, including manufacturers and distributors; to applicators, who rely on the label for use instructions and hazard and safety information; and to the general public. *Id.*

EPA's regulations govern not only the size, format, and location of the label but also its contents. *See, e.g.*, 40 C.F.R. § 156.10. Pesticide labels convey information such as application rates, application intervals, and required personal protective equipment. Many other details are required, such as the product's contents, the sites of application, the target pests, and application methods.

The label also contains important health and safety information, such as the applicable acute toxicity category and associated signal word determined by EPA (*see* 40 C.F.R. §§ 156.62, 156.64) and hazard and precautionary statements for humans and domestic animals (40 C.F.R. §§ 156.70-156.78) and for the environment, including non-target organisms (40 C.F.R. §§ 156.80-156.85). Hazard and precautionary statements for humans and domestic animals include information on first aid, in case of unintended exposure to the pesticide. *See* 40 C.F.R. § 156.68. The label must also include directions for storage, residue removal, and disposal of the pesticide

[5] https://www.epa.gov/pesticide-labels/label-review-training-module-1-label-basics-page-3.

[6] https://www.epa.gov/system/files/documents/202412/label_review_manual_12122024.pdf.

and its container (*see, e.g.*, 40 C.F.R. §§ 156.140, 156.144, 156.146, 156.156). EPA will not approve a proposed label or grant a registration if the label is missing any required information. *e.g.*, 40 C.F.R. §§ 156.10(a)(1), 152.112(f).

FIFRA prohibits distributing or selling a misbranded pesticide. A pesticide may be misbranded if its labeling bears false or misleading statements, if its label omits necessary warnings, or if required label or labeling information is not prominently placed. 7 U.S.C. §§ 136j(a)(1)(E), 136j(a)(2)(A), 136(q)(1)(A), (E), (G). EPA's regulations generally require amended registration (subject to EPA approval) before a registrant may distribute or sell a product with a label different from that approved by EPA. *See generally*, *Durnell*, 609 U.S. at 383-86. Distributing or selling a misbranded pesticide may result in civil or criminal penalties as well as stop sale, use, and removal orders and seizure. *Durnell*, 609 U.S. at 378 (citing 7 U.S.C. §§ 136J(A)(1)(e), 136*l*).

With narrow exceptions for certain "minor" modifications, once the label is approved as part of pesticide registration, "any modification in the . . . labeling . . . of a registered product must be submitted with an application for amended registration . . . [and such] application must be approved by the Agency before the product, as modified, may legally be distributed or sold." 40 C.F.R. §§ 152.44(a), (c). Changes in precautionary statements are not "minor modifications" and must be approved in advance by EPA.[7] *See Durnell*, 609 U.S. at 405 n.5; *Schaffner v. Monsanto Corp.*, 113 F.4th 385, 384 n.11 (3d Cir. 2024).

II. EPA's Review of Glyphosate-Based Products

EPA approves a pesticide label only after exhaustive review of the best available science relating to the pesticide's effects on safety and human health. EPA's Pesticide Registration Manual explains that "[b]efore any pesticide product that EPA has not exempted from registration

[7] EPA, Office of Pesticide Programs, Pesticide Registration Notice 98-10: Notifications, Non-Notifications and Minor Formulation Amendments at 8 (Oct. 22, 1998), https://tinyurl.com/mtycc4bp.

requirements can be lawfully sold or distributed, EPA performs a rigorous, comprehensive scientific assessment of the product, resulting in a registration decision."[8]

FIFRA and its implementing regulations require registrants to provide substantial scientific data to support a pesticide's safety and health effects. 7 U.S.C. §§ 136a(c)(1)(F), (c)(2)(A); 40 C.F.R. § 158.500(d) (toxicology data requirements); *see generally* 40 C.F.R. pt. 158. There are substantial data requirements addressing the toxicology of the pesticide, including studies relating to the likelihood that a particular pesticide could cause cancer in laboratory rodents. 40 C.F.R. § 158.500(d). EPA regulations require registrants to satisfy data requirements covering a broad range of additional topics, such as: the physical and chemical makeup of the pesticide; the acute, sub-chronic, and chronic toxicity of the pesticide; the effect of the pesticide on various plants and animals; and the degree to which humans will be exposed to the pesticide during its intended use. *See, e.g.*, 40 C.F.R. pt. 158.

EPA "requires robust evidence of a pesticide's potential carcinogenicity as a part of registration," *Durnell*, 609 U.S. at 405 n.5, and uses registration data to identify the potential for various adverse effects such as neurotoxicity, reproductive and developmental toxicity, immunotoxicity, and as relevant here, cancer. *E.g.*, 40 C.F.R. § 158.500(e)(19) (prescribing minimum acceptable study durations for studies that combine chronic oral toxicity and carcinogenicity); 40 C.F.R. §§ 158.1000–1070 (testing for human exposure); s*ee also, e.g.*, EPA Health Effects Test Guideline 870.4200 (Carcinogenicity);[9] EPA, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005).[10] EPA develops dose-response assessments (determining the relationship between the dose and potential toxic effects) for a wide variety of species (*e.g.*, humans to fish) and a wide variety of potential responses (*e.g.*, acute effects on skin or eyes,

[8] *See* EPA Pesticide Registration Manual: Introduction, https://www.epa.gov/system/files/documents/2021-08/pesticide-registration-manual-introduction.pdf.

[9] *See* https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0020.

[10] *See* https://perma.cc/86MQ-MG3W.

chronic neurological or reproductive effects, and carcinogenicity). *E.g.*, 40 C.F.R. § 158.130 ("Purposes of the registration data requirements").

In light of these rigorous standards, EPA's decision *not* to require a cancer warning for glyphosate-based pesticides was no accident. It was the result of decades of evaluation of the relevant scientific evidence. The approved label reflects EPA's repeated conclusion that glyphosate-based pesticides *are not likely to be carcinogenic to humans*. EPA issued its initial glyphosate registration in 1974 and issued a Reregistration Eligibility Decision for the active ingredient glyphosate in 1993 after a thorough examination of the underlying data.[11] In more than 50 years since the original registration, EPA has concluded again and again that glyphosate does not pose a cancer risk to humans.

Acting on the recommendation of a scientific peer review committee in the early 1990s, EPA found "evidence of non-carcinogenicity for humans."[12] The Agency reiterated that finding in a formal rule in 1997 and again in subsequent rulemakings.[13]

In 2009, EPA opened its most recent registration review, which has entailed an extensive review of glyphosate's environmental safety and toxicology data after numerous rounds of public notice and comment. After review by both EPA's Cancer Assessment Review Committee and a Scientific Advisory Panel, EPA published a Revised Glyphosate Issue Paper evaluating the pesticide's carcinogenic potential.[14] This extensive review of "new science" included assessment of "63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies for the active ingredient glyphosate."[15] EPA concluded that "available data and weight-

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[11] *See* EPA, *Ingredients Used in Pesticide Products: Glyphosate*, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate; EPA, *Reregistration Eligibility Decision (RED): Glyphosate* (Sept. 1993), https://tinyurl.com/4rewtdnp.

[12] *See* EPA, R.E.D. Facts, Glyphosate, at 2 (Sept. 1993), https://tinyurl.com/4rpwv9bz.

[13] Final Rule: Glyphosate; Pesticide Tolerances, 62 Fed. Reg. 17,723, 17,724 (Apr. 11, 1997); *see also* Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,936 (Sept. 27, 2002); Final Rule: Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

[14] *See* EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017), https://tinyurl.com/56xb5bed.

[15] *Id.* at 144.

of-evidence clearly do not support the descriptors 'carcinogenic to humans'" or "'likely to be carcinogenic to humans.'"[16] Instead, the scientific evidence most strongly supports the description "not likely to be carcinogenic to humans."[17] *Durnell*, 609 U.S. at 371.

Notably, EPA concluded this assessment *after* the International Agency for Research of Cancer (IARC) announced its view, upon which glyphosate plaintiffs nationwide base their claims, that glyphosate was a probable carcinogen. *Id.* at 379-381. EPA's scientific review led to its Draft Human Health Risk Assessment, which, after notice and comment, concluded that glyphosate was not likely to cause cancer.[18] After considering thousands of public comments, EPA issued its "Proposed Interim Registration Review Decision," reaffirming that its "independent evaluation of the carcinogenic potential of glyphosate . . . has determined that glyphosate is 'not likely to be carcinogenic to humans.'"[19] EPA expressly rejected IARC's cancer conclusion, explaining that EPA's "cancer evaluation is more robust than IARC's evaluation," which "only considered a subset of the studies included in the EPA's evaluation" and included "some studies that were not appropriate for determining the human carcinogenic potential of glyphosate."[20]

After this extensive process, EPA's Office of Pesticide Programs sent an August 2019 letter to all glyphosate registrants reiterating that it "disagrees with IARC's assessment of glyphosate."[21] EPA noted that its cancer classification is "consistent with other international expert panels and regulatory authorities," including government regulators in Canada, Australia,

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[16] *Id.*

[17] *Id.*

[18] *See* EPA, Glyphosate: Draft Human Health Risk Assessment in Support of Registration Review, Case No. 0178 (Dec. 12, 2017), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0068.

[19] *See* EPA, Glyphosate: Proposed Interim Registration Review Decision, Case No. 0178, at 7 (Apr. 2019), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344.

[20] *Id.*

[21] EPA, Letter to Glyphosate Registrants on California Proposition 65, at 1 (Aug. 7, 2019) ("EPA Letter"), https://tinyurl.com/53eb7685.

and New Zealand, as well as the European Food Safety Authority and European Chemicals Agency.[22] *See Durnell*, 609 U.S. at 381-82. EPA notified registrants that glyphosate-based products that *do* bear a cancer warning would be "misbranded pursuant to" FIFRA.[23]

In January 2020, following another comment period, EPA issued its interim registration review decision, reaffirming its longstanding conclusion that glyphosate does not cause cancer in humans.[24] Even after that determination was vacated by the Ninth Circuit, s*ee Nat. Res. Def. Council v. EPA*, 38 F.4th 34, 52 (9th Cir. 2022), EPA continues to approve labels without requiring a cancer warning.[25] Indeed, in subsequent proceedings, EPA has emphasized that its "scientific findings regarding glyphosate, including its longstanding finding that glyphosate is not likely to be carcinogenic to humans" may still be used "as support for a future decision."[26] As the Supreme Court summarized: "All told, in accordance with EPA's view that glyphosate is not likely to cause cancer in humans, EPA has not required glyphosate-based pesticides like Roundup to include a cancer warning on their labels." *Durnell*, 609 U.S. at 381.

ARGUMENT

I. Plaintiffs' Claims are Preempted to the Extent They Rely on a Failure-to-Warn Legal Theory.

After extensive review of this regulatory framework and EPA's application of it in approving glyphosate-based pesticide labels, the Supreme Court confirmed in *Durnell* that FIFRA's Uniformity provision preempts "*any state tort claim* that would require a pesticide

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[22] *See also, e.g.*, European Food Safety Authority, Glyphosate: no critical areas of concern; data gaps identified (July 6, 2023) (European Chemicals Agency concluding that glyphosate "did not meet the scientific criteria to be classified as a carcinogenic, mutagenic or reprotoxic substance"), https://tinyurl.com/ywbkvdus; European Chemicals Agency, Glyphosate: no change proposed to hazard classification (May 30, 2022) ("classifying glyphosate as a carcinogen is not justified"), https://tinyurl.com/yeywmrfz.

[23] EPA Letter 1.

[24] *See* EPA, Glyphosate: Interim Registration Review Decision, Case No. 0178, at 5 (Jan. 2020), https://tinyurl.com/2s9ht99v.

[25] *See* Chemical Name: Glyphosate, EPA, https://perma.cc/N8KY-7KJ5.

[26] *Supra*, n.26.

manufacturer to use a label" other than "the EPA-approved label[.]" 609 U.S. at 390. The Court thus held that FIFRA expressly preempted a Missouri state common law "failure-to-warn" claim. This holding, however, broadly applies to "any state court claim" alleging that pesticide manufacturers should have affixed customer warnings to pesticide product labeling "that would impose labeling requirements 'in addition to' or 'different from' those required under FIFRA." *Id*. at 386.

Plaintiffs cannot repackage their failure-to-warn theories as different torts and expect a different result. It is the "heart of" the claim that matters, regardless of the tort theory espoused. *Id*. at 383. The Supreme Court previously applied this principle to FIFRA's Uniformity provision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). There, the Court held that FIFRA express preemption hinges on "an examination of the elements of the common-law duty at issue[,]" and whether petitioners' various claims were "premised on common law rules that qualify as 'requirements for labeling or packaging.'" *Id*. at 445-447. Thus, for instance, the Court determined the state law fraud claims imposed requirements for pesticide labels, which "must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards" when determining whether or not a proposed requirement is "in addition to or different from" those required by EPA. *Id*. at 453. Conversely, the Court indicated that "genuine" design defect claims—wholly untethered from failure-to-warn allegations—do not constitute a labeling "requirement" for purposes of § 136v(b). *Id*. at 445.[27]

Courts must thus look to a claim's substance and not its form when applying FIFRA's Uniformity provision post-*Durnell*. Properly viewed in that light, the negligence, design defect and breach of warranty counts included in the Plaintiffs' complaints are little more than dressed-up failure-to-warn claims challenging the content of the EPA-approved labeling. *See* Monsanto Fla. Br. at 12-16, Dkt. 22524; Monsanto Oh. Br. at 7-8, Dkt. 22530; Monsanto N.C. Br. at 8-9, Dkt. 22529; Monsanto Ga. Br. at 9, Dkt. 22523; Monsanto Miss. Br. at 7-8, Dkt. 22525. If decided against Monsanto, these claims would require Monsanto to alter or amend EPA-approved

[27] *Bates* did not, however, address failure-to-warn claims such as those asserted by Plaintiffs, disguised as design defect claims or related torts.

disclosures provided in FIFRA labeling to provide a cancer warning that EPA, after extensive review of the science, has determined is unnecessary to protect human health. Because the claims would interfere with EPA's expert labeling decisions, FIFRA expressly preempts each of these claims. Further litigation based on theories, however named, that the Plaintiffs have not been fairly warned of the cancer risks of glyphosate-based pesticides, would be futile.

A. Plaintiffs' Negligence Claims Impose Labeling Requirements in Addition to or Different From EPA's and Are Therefore Preempted.

Plaintiffs asserting negligence claims in a products liability action must demonstrate, at minimum, a duty and breach of that duty under Florida, Ohio, North Carolina, Mississippi, or Georgia law. *Marzullo v. Crosman Corp.*, 289 F. Supp. 2d 1337, 1342 (M.D. Fla. 2003); *Rheinfrank v. Abbott Lab'ys, Inc.*, 119 F. Supp. 3d 749, 761 (S.D. Ohio 2015), *aff'd*, 680 F. App'x 369 (6th Cir. 2017); *Durkee v. C.H. Robinson Worldwide, Inc.*, 765 F. Supp. 2d 742, 758 (W.D.N.C. 2011); *McSwain v. Sunrise Med., Inc.*, 689 F. Supp. 2d 835, 846 (S.D. Miss. 2010); *Wheeler v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 1344, 1353 (S.D. Ga. 2013).

But as applied here, Plaintiffs' negligence claims rest principally on a breach of a duty to warn—the very same duty at issue in *Durnell* cloaked under the umbrella of general "negligence." Plaintiffs allege that Monsanto breached its duty to include a cancer warning on Roundup®'s label and/or packaging. *See, e.g.*, Monsanto Ga. Br. at 9, Dkt. 22523 (claims allege that Monsanto is liable for "failing to adequately and correctly warn . . . of the dangers of Roundup" and for "[f]ailing to provide adequate cautions and warnings to protect the health of [Roundup] users.") A lay jury imposing this duty on manufacturers would directly undermine EPA's determination as to the adequacy of a pesticide product's labels and/or packaging in the same way that Missouri's duty-to-warn tort claim did in *Durnell*. For the same reason as explained by *Durnell*, Plaintiffs' negligence claims impose "requirements" that are different from or in addition to EPA's labeling requirements and are thus preempted by FIFRA's Uniformity provision. 7 U.S.C. § 136v(b).

B. Plaintiffs' Design Defect Claims Impose Labeling Requirements in Addition to or Different From EPA's and Are Therefore Preempted.

Plaintiffs' design defect claims similarly rest on their alleged lack of knowledge of Roundup®'s alleged dangerous characteristics. *See, e.g.*, Monsanto Ga. Br. at 9, Dkt. 22523 (alleging Roundup® is "defective to an extent beyond that which an ordinary consumer would anticipate, and Plaintiffs lacked "knowledge of Roundup's dangerous characteristics"). Such claims are inextricably linked to the product's EPA-mandated labeling. To establish these claims, Plaintiffs must either prove that the product failed to perform as safely as an ordinary consumer would expect pursuant to the consumer-expectations test, or, through a risk-utility analysis, that a reasonable, feasible alternative design would have reduced or avoided the relevant risk. *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 504, 511 (Fla. 2015); *Zang v. Cones*, 34 N.E.3d 955, 961 (Ohio App. 2015); *Sparks v. Oxy-Health LLC*, 134 F. Supp. 3d 961, 987–88 (E.D.N.C. 2015); *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 673–75 & n.6 (Ga. 1994); *Elliott v. El Paso Corp.*, 181 So. 3d 263, 271–72 (Miss. 2015). Under either analysis, EPA's approval of Roundup®'s labeling is fatal to Plaintiffs' claims.

Because consumer expectations regarding a scientifically complex product are informed by its warnings, a consumer cannot expect that product to perform more safely than government-mandated warnings indicate. *Papike v. Tambrands Inc.*, 107 F.3d 737, 743 (9th Cir. 1997). Liability based on consumer expectations that vary from what is plainly provided in the EPA label (here, no cancer warning) would require a manufacturer to amend the label to provide a warning that EPA has not required. Such liability would frustrate the uniformity explicitly protected and promoted by FIFRA. *See, e.g.*, *Oken v. Monsanto Co.*, 218 F. Supp. 2d 1361 (S.D. Fla.2002) (consumer expectations test necessarily involves consideration of warnings given to the public, and thus, a design defect claim on this theory is preempted by FIFRA).

Similarly, the risk-utility test contemplates that the jury will consider the adequacy of a product's warnings in weighing the risks of a product against the product's benefits. This consideration of a pesticide product's warnings under state law is precisely what is prohibited by FIFRA. The risk-utility analysis considers feasibility, the availability of a safer effective substitute, cost, and the alternative's adverse effects. But when "unreasonable danger" rests on consumers' lack of knowledge of an alleged cancer risk, the theory necessarily seeks a warning

different from the EPA-approved label. Feasible alternatives must, to a reasonable probability, have prevented the harm without impairing the product's utility, usefulness, practicality, or desirability. When plaintiffs instead allege that Roundup® "as labeled" was more dangerous than ordinary consumers would contemplate, the alleged product defect is *the missing cancer warning*.

In all relevant states, Plaintiffs' design defect claims would impose inconsistent or additional labeling requirements in violation of FIFRA's Uniformity provision when, as here, their underlying theory rests on inadequate pesticide safety warnings. FIFRA expressly preempts such claims.

C. Plaintiffs' Warranty Claims Impose Labeling Requirements In Addition to or Different From EPA's and are Therefore Preempted.

Plaintiffs' warranty claims are also tethered to Monsanto's mandatory Roundup® labeling. Express warranty claims based on EPA-required label statements are preempted because they would impose liability for federally mandated labeling, while implied warranty claims are preempted to the extent they require a warning or other risk statements different from the EPA-approved labeling.

"Breach of express warranty claims are preempted to the extent they are based upon inadequacies in labeling or packaging." *Jarman v. United Indus. Corp.*, 98 F. Supp. 2d 757, 765 (S.D. Miss. 2000) (applying *Papas v. Upjohn Co.*, 985 F. 2d 516 (11th Cir. 1993)). Such claims arising from *voluntary* statements generally are not. *Id.* But EPA *requires* pesticide registrants to use the precise label approved in EPA's review process—statements contained therein are not "voluntarily undertaken." *Durnell*, 609 U.S. at 378 ("after EPA has registered the pesticide and approved the label, the manufacturer is required to use that label").

Implied warranties arise by operation of state law and impose an agreement to be held responsible for a product that is not fit for the use and purposes intended. *Papas v. Upjohn Co.*, 985 F.2d 516, 519-520 (11th Cir. 1993). Here, Plaintiffs allege that Monsanto failed to disclose a risk of cancer associated with Roundup® use. *See, e.g.*, Monsanto Ga. Br. at 9, Dkt. 22523. This claim implies that the labeling and packaging failed to warn the user and necessarily questions the adequacy of Roundup®'s label. *Papas*, 985 F.2d at 520 ("to the extent the implied warranty

claim depends upon inadequacies in labelling or packaging, FIFRA section 136v preempts the claim").

Plaintiffs' warranty claims would impose labeling requirements that are inconsistent with the EPA-approved Roundup label, and they are therefore preempted. *See also*, *Lowe v. Sporicidin Int'l*, 47 F.3d 124, 130 (4th Cir. 1995) (applying *Papas*, 985 F.2d 516); *Jenkins v. James B. Day & Co.*, 69 Ohio St.3d 541 (1994) (acknowledging the holding in *Papas*).

II. Durnell Applies to All FIFRA "Labeling," Not Merely the Container "Label."

Post-*Durnell*, the MDL Plaintiffs have attempted to shift the focus of their claims from the Roundup® label to off-label statements such as advertisements "convey[ing] the false and misleading message that Roundup was perfectly safe for use without any protective clothing or concern about dermal exposure." Pl.'s Opposition at 13, Dkt. 22682. However, FIFRA preemption applies with equal force to certain materials accompanying the pesticide—not just the label itself.

FIFRA explains that pesticide's "label" is simply one form of the broader category of "labeling" covered by the Uniformity provision. A pesticide "label" is "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). But a pesticide's "labeling" is broader and encompasses not only "all labels" but also all other written, printed, or graphic matter that accompanies the pesticide "at any time," as well as matter referenced on the label or in literature accompanying the pesticide, subject to specified exceptions for certain official publications. 7 U.S.C. § 136(p)(2). Thus, labeling extends well beyond the words printed on or attached to the container.

Pesticide labeling is central to EPA's registration and registration-review processes. For example, when a pesticide label refers to a procedural manual, that manual also constitutes "labeling" that EPA must approve and that users must follow. EPA reviews pesticide labeling to ensure that required health and safety warnings are adequate and that the labeling contains no false or misleading statement concerning the pesticide or its ingredients. 7 U.S.C. §§ 136(q)(1)(A), (G). Plaintiffs' negligence, warranty, and design defect theories are therefore preempted to the extent they seek to impose requirements to communicate a cancer warning

through written, printed, or graphic matter qualifying as FIFRA labeling. *See, e.g.*, Monsanto Ga. Br. at 9, Dkt. 22523 ("Plaintiff Moreland … contends he may still advance a claim for 'failure to warn (excluding label."). *Durnell*, 609 U.S. at 389 ("FIFRA expressly directs EPA to register pesticides and 'determin[e]' that the pesticide's 'labeling' complies with FIFRA's many specific requirements.").

Plaintiffs likewise cannot evade FIFRA preemption by recasting their failure-to-warn theory as deceptive advertising claims. A state law duty to provide a cancer warning in pesticide advertising conflicts with FIFRA when it differs substantially from claims EPA-approved in the product's registration and is made as part of the product's distribution or sale (including offers for sale). 7 U.S.C. § 136j(a)(1)(B); 40 C.F.R. § 168.22. Even where such advertising material is not technically "labeling," FIFRA still preempts claims that would require such advertising to conflict with EPA's label approval. FIFRA explicitly prohibits the distribution and sale of "any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration." 7 U.S.C. § 136j(a)(1)(B). Here, requiring a cancer warning in pesticide advertising would substantially differ from the claims that EPA- approved in connection with Roundup®'s registration.

State law cannot require what Section 136j(a)(1)(B) explicitly prohibits. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (implied preemption where it is "impossible" for defendant simultaneously "to comply with both state and federal requirements"); *Papas v. Upjohn Co.*, 985 F. 2d 516 (11th Cir. 1993) ("Because claims challenging the adequacy of warnings on materials other than the label or package of a product necessarily imply that the labeling and packaging failed to warn the user, we conclude that these claims are also pre-empted by FIFRA.") Thus, for instance, EPA has concluded that glyphosate-based products bearing the California Proposition 65 cancer warning would be misbranded pursuant to FIFRA.[28]

[28] *See* EPA Letter, *supra*, n. 23.

Accordingly, Plaintiffs cannot simply pivot to labeling or sale-related advertising as alternative vehicles for FIFRA's regulatory framework.

III. To the Extent Plaintiffs Assert "Genuine" Design Defect Claims, They are Impliedly Preempted.

A. Plaintiffs' Design Defect Claims are Preempted Because They Would Effectively Require Manufacturers to Withdraw from the Pesticide Market.

As already noted, the Supremacy Clause preempts state law where "compliance with both federal and state regulations is a physical impossibility[.]" *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 204 (1983) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963)). Plaintiffs' design defect claims seek to impose a duty on Monsanto to unilaterally change the formulation for Roundup®. But this is not permitted under FIFRA. For reasons similar to that applied to duty-to-warn claims in *Durnell*, such design defect claims are preempted. *Bartlett*, 570 U.S. at 475-476 (2013). They would effectively require manufacturers to pull their products from the market for complying with EPA's product formulation.

Pesticide products require EPA approval, which requires EPA to assess and approve not only the product label but also its composition. The very same regulation that *Durnell* read to mean that "federal law requires Monsanto to sell Roundup® with the label that EPA-approved[,]" and without modification absent EPA approval, also requires EPA approval to change the pesticide's composition. *See Durnell*, 609 U.S. at 385; 40 C.F.R. § 152.44 ("[A]ny modification *in the composition*, labeling, or packaging of a registered product must be submitted with an application for amended registration.") (emphasis added). *Durnell* itself makes it clear that pesticide registrants cannot unilaterally alter their pesticide products' formula without EPA approval. *See id.* at 378 n.1 ("FIFRA prohibits selling a pesticide if its 'composition' differs from the composition described at registration.") (quoting 7 U.S.C. § 136j(a)(1)(C)). Thus, under *Durnell*, just as federal law "require[s] a manufacturer to use the EPA-approved label and prohibit[s] the manufacturer from unilaterally changing the label," *id.* at 391, federal law requires Monsanto to use the EPA-approved formulation and prohibits Monsanto from unilaterally

changing the formulation. The effect is the same—state law claims that would require a change to that EPA-approved formulation without EPA approval are preempted.

EPA's risk determinations for glyphosate-based products thus preempt state-tort liability based on allegations that such products were or are "unreasonably dangerous." This assertion's corollary—that Monsanto must simply stop selling these products—is equally flawed and "incompatible with" federal preemption jurisprudence, which recognizes that a company "is not required to cease acting altogether in order to avoid liability." *Bartlett*, 570 U.S. at 488.

B. Plaintiffs' Design Defect Claims are Impliedly Preempted Because They Disrupt the Regulatory Scheme for Pesticides Envisioned by Congress.

In *Durnell*, the Court recognized the pervasiveness of EPA's regulation of pesticide products pursuant to FIFRA. Plaintiffs' threadbare design defect allegations targeting Roundup®'s formulation, as opposed to its labeling, are inconsistent with the structure and purpose of this framework and, therefore, are impliedly preempted. A state law claim is impliedly preempted where it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). Although the focus of *Durnell* was express preemption, the Court's discussion of FIFRA and the logic of its opinion also compels the conclusion that Plaintiffs' design defect claims are an "obstacle" to Congress's purposes in enacting FIFRA and delegating exclusive authority over pesticide registration to the EPA.

The Supreme Court in *Durnell* recognized that Congress created a "carefully calibrated and EPA-centric regulatory scheme" when it enacted FIFRA and acknowledged EPA's broad authority "to monitor a pesticide's continued safety and order appropriate changes such as a new label[.]" 609 U.S. at 380. *See also*, *id.* at 386 ("[W]hen it comes to safety claims, EPA's registration determinations do reflect EPA's considered judgment that a pesticide's label is not false or misleading and contains all necessary warnings.") The Court commented that state tort law claims attacking EPA-approved labels improperly "upend FIFRA's carefully calibrated and EPA-centric regulatory scheme[,]" which grants the EPA powers to police pesticide safety, such as removing a product from the market through "registration cancellation ... proceedings[,]" the

right to seek "civil or criminal penalties if a manufacturer fail[s] to inform EPA of important new safety-related information[,]" and other carefully crafted statutory remedies. *Id*. at 391.

State tort law claims seeking to modify a registered pesticide's formulation undermines EPA's determination that the pesticide does not cause cancer or otherwise pose unreasonable risks to man or the environment. The Supreme Court has held that when a federal agency has approved a product's design as safe when used according to label instructions, as is the case here, design defect claims are impliedly preempted. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000) (federal regulation which permitted, but did not require, airbags to be installed in passenger vehicles preempted claims that a car was defective because it lacked an airbag). While the Supreme Court has begun to back away from finding implied obstacle preemption, this doctrine still applies where a "significant objective" of the regulatory scheme is frustrated. *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 326 (2011). Post-*Durnell*, "EPA's comprehensive and exclusive authority in registering pesticides and approving labels" is abundantly clear, and cannot be derailed.

Any claims targeting the composition of glyphosate-based products are at direct odds with EPA's decision to grant Monsanto a registration for Roundup®. Those claims also undermine FIFRA's specified enforcement mechanisms and avenues for removing pesticides from the market.[29] Plaintiffs purported design defect claims would foreclose what the EPA has authorized, and they are therefore preempted by FIFRA.

CONCLUSION

For all of these reasons, Plaintiffs' disguised and repackaged state law claims are preempted for the same reason the failure-to-warn claims were preempted in *Durnell* and because

[29] FIFRA provides for an administrative proceeding involving a cancellation hearing where the proponent can present its case for cancellations. *See, e.g.*, 7 U.S.C. § 136d(b). Alternatively, FIFRA also allows state legislation to "regulate the sale or use of any federally registered pesticide," 7 U.S.C. § 136v(a), including by prospectively "ban[ning]a pesticide within its borders[.]" *Durnell*, 609 U.S. at 380, n.2.

those claims would also be preempted under conflict and obstacle preemption. Summary judgment should be granted on those state law claims to Monsanto.

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Respectfully submitted,

By: s/ *Melanie Ayerh*

Melanie Ayerh, Esq.

Counsel for Amicus Curiae CropLife America