IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
SAVANNAH DIVISION

JOHN D. CARSON, SR.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 4:17-cv-00237-RSB-CLR
	)	
MONSANTO COMPANY,	)	ORAL ARGUMENT REQUESTED
	)	
Defendant.	)	

DEFENDANT MONSANTO COMPANY'S MOTION FOR JUDGMENT ON THE PLEADINGS AND SUPPORTING MEMORANDUM

Pursuant to Federal Rule of Civil Procedure 12(c), Defendant Monsanto Company ("Monsanto") moves for judgment on the pleadings. The state-law claims at issue in this litigation fail because they are expressly and impliedly preempted by federal law. Accordingly, Monsanto requests that the Court grant Monsanto's motion, dismiss this case, and close this civil action. The grounds for Monsanto's motion are set forth below.

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INTRODUCTION

The central claim in this case is that state law required Monsanto to warn that glyphosate, the key ingredient in its Roundup® brand herbicide products ("Roundup®"), causes cancer. But the Environmental Protection Agency ("EPA") has exhaustively reviewed the science, determined that glyphosate does *not* cause cancer, and consistently approved Roundup® for sale with a label that does *not* warn of cancer. As EPA often puts it, "the label is the law." Yet to comply with Plaintiff John D. Carson's ("Plaintiff's") view of state law, Monsanto would have had to violate federal law—specifically, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")—by changing the label to one that has not been approved by EPA and that includes a warning for a risk EPA does not believe exists. That is a paradigmatic case of federal preemption.

EPA's consistent and repeated determination that no cancer warning is warranted has long preempted any state-law requirement to the contrary, but, in August 2019, EPA removed any possible basis to doubt that conclusion. The agency not only confirmed its determination that "glyphosate is 'not likely to be carcinogenic to humans,'" Ex. A, EPA, Off. of Pesticide Programs, Letter to Glyphosate Registrants Regarding Labeling Requirements at 1 (August 7, 2019) ("EPA Letter"), but went further and informed registrants, including Monsanto, that it would refuse to approve a cancer warning for glyphosate products like Roundup®. *Id.* EPA explained that including such a cancer warning would make glyphosate products "misbranded" in violation of FIFRA. *Id.* And consistent with that determination, the United States government recently filed an amicus brief urging that claims similar to the present ones be rejected as preempted by federal law. Ex. B, Brief for United States as Amicus Curiae Supporting Appellant at 1, *Monsanto Co. v. Hardeman*, No. 19-16636 (9th Cir. Dec. 20, 2019) ("U.S. Br.").

Preemption should end this case too. In light of EPA's unequivocal determination that a cancer warning would be unwarranted and illegal, there is no need for either the parties or this

Court to continue on a lengthy and burdensome process of discovery and ultimately trial. This Court should reach the same conclusion that the United States has reached: state-law claims requiring a cancer warning on the Roundup® label are preempted.

Specifically, Plaintiff's claims are preempted in two ways. *First*, the claims are expressly preempted. To ensure national uniformity and avoid a patchwork of labeling regimes across the fifty states, Congress has forbidden States to impose on pesticide manufacturers "any requirements for labeling or packaging in addition to or different from" the requirements under FIFRA. 7 U.S.C. § 136v(b). And as EPA recently affirmed, a glyphosate product bearing the cancer warning Plaintiff here demands would "not meet the requirements of FIFRA." Ex. A, EPA Letter at 1. The state-law duty on which Plaintiff's claims are based is undeniably "different from" the labeling requirements of FIFRA.

Second, Plaintiff's claims are impliedly preempted. Implied conflict preemption applies when it is impossible to comply with both state and federal law. In particular, where federal law prohibits an action purportedly required by state law without federal agency approval, and there is "clear evidence" the agency would not grant that approval, the state-law claim is preempted. Monsanto cannot add a cancer warning to Roundup® without EPA approval. And there could hardly be clearer evidence that EPA would deny such approval—because EPA has said so.

Whether analyzed under FIFRA's express preemption clause or principles of impossibility preemption, the bottom line is simple and straightforward. An expert federal agency, charged by Congress with evaluating the safety of pesticides, has for decades considered the science and concluded that glyphosate does not pose a cancer risk. Plaintiff wants a lay jury to decide that the opposite is true, and to enforce a supposed state-law duty to issue a warning that the expert federal

agency has determined to be "false and misleading" and in violation of federal law. The claims in this case are preempted, and the complaint should be dismissed.

BACKGROUND

A. Statutory and Regulatory Framework.

Under FIFRA, all pesticides[1] sold in the United States must be registered with EPA. 7 U.S.C. § 136a(a). Before registering a pesticide, EPA must determine, among other things, that the pesticide will not cause "unreasonable adverse effects on the environment," *id.* § 136a(c)(5)(C), which FIFRA defines to include an unreasonable adverse effect on human health, *id.* § 136(bb). EPA also must determine that the pesticide is not "misbranded," meaning that its label contains adequate instructions for use, includes all necessary warnings or cautionary statements, and is not "false or misleading in any particular." *Id.* § 136(q)(1)(A), (F), (G); *id.* § 136a(c)(5)(B); 40 C.F.R. § 156.10(a)(5)(ii). At least once every fifteen years, EPA reevaluates whether a pesticide continues to satisfy the FIFRA standard for registration through a registration review process, which includes public notice and comment on the underlying science. *See* 7 U.S.C. § 136a(g); 40 C.F.R. §§ 155.50, 155.52.

FIFRA and its implementing regulations require pesticide registrants to provide voluminous scientific data, including field trial data, which EPA analyzes in determining whether to approve a proposed label. *See* 7 U.S.C. §§ 136a(c)(1)(F), (c)(2)(A), 136c(a). Prior to making that determination, EPA must consider this information along with submissions and studies of health risks, including carcinogenicity and toxicity. *See id.* § 136a(c)(5)(B); 40 C.F.R. § 158.500. In approving a pesticide label, EPA exercises its expert judgment both about those scientific issues and other mandatory label provisions intended to protect applicators and others. 40 C.F.R. §

[1] The term "pesticide" as used in the statutes and regulations—and in this brief—includes herbicides. *See* 7 U.S.C. § 136a(u).

152.112(f). EPA-mandated label provisions relevant to health and safety include "human hazard" and "precautionary statements" warnings about potential health risks and mitigation actions (*id.* §§ 156.60–156.70); mandatory personal protective equipment (*id.* § 156.212); detailed application directions to protect human health and safety (*id.* § 156.10(i)(2)); and designation for use by "general" or "certified applicators" based on possible health, safety, or other risks (7 U.S.C. § 136a(d); 40 C.F.R. § 156.10(j)).

Once EPA has approved a registration and the associated label, "[t]he label is the law," as EPA often puts it.[2] Any change to the approved labeling requires EPA approval. *See, e.g.*, 40 C.F.R. § 152.44 ("Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration.").

FIFRA limits the ability of States to adopt their own labeling requirements for pesticides. Under the heading "Uniformity," the statute includes an express preemption provision prohibiting states from "impos[ing] . . . any requirements for labeling or packaging in addition to or different from those required under this Act [*i.e.*, FIFRA]." 7 U.S.C. § 136v(b). FIFRA defines "labeling" broadly to include both the label itself and "all other written, printed, or graphic matter" that "accompany[]" the pesticide at any time. *Id.* § 136(p)(2).

B. EPA's Approval of Roundup® and Consistent Determination That Glyphosate Does Not Pose a Cancer Risk.

Monsanto is the manufacturer of Roundup®. Compl. ¶ 4. The active ingredient in many Roundup® products is glyphosate, a broad-spectrum herbicide "used in a wide variety of

[2] *See, e.g.*, Ex. C, EPA, Pesticide Registration Manual: Introduction at 2 (last updated April 2018). Along with the EPA Letter and U.S. Br., official EPA documents (other than those available in the Federal Register) are attached as exhibits for the Court's convenience. As explained, *infra* p. 14, all of these documents are subject to judicial notice.

herbicidal products around the world." *Id.* ¶¶ 10, 12, 71(d). Roundup® was first approved for sale in the 1970s and has been in wide use for "nearly 40 years." *Id.* ¶¶ 12–13.

In the course of its registration decisions, EPA repeatedly has evaluated the potential human health risks of glyphosate. That review has considered "epidemiological data" on "human exposure to glyphosate formulations." Ex. D, EPA, Off. of Chemical Safety and Pollution Prevention, Response to the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on the Evaluation of the Human Carcinogenic Potential of Glyphosate at 3 (Dec. 12, 2017); *see* Ex. E, EPA, Glyphosate Proposed Interim Registration Review Decision at 10 (April 2019) (EPA review of glyphosate included studies of glyphosate in "multiple formulations"). And each time, after reviewing the available scientific studies, EPA has concluded that glyphosate does not pose a risk of cancer in humans.[3] Indeed, EPA has classified glyphosate in its lowest risk category since at least 1991. For example:

- In 1991, EPA classified glyphosate as non-carcinogenic for humans "based on the lack of convincing evidence of carcinogenicity in adequate studies." Ex. G, EPA, Glyphosate: Reregistration Eligibility Decision (R.E.D.) Facts at 2 (Sept. 1993).[4]

- In 2002, in response to a challenge to glyphosate's safety, EPA found "[n]o evidence of carcinogenicity." Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,935–43 (Sept. 27, 2002).

[3] In addition to its findings with respect to glyphosate—the active ingredient in Roundup® —EPA separately has concluded that the inert ingredients in Roundup® do not pose a risk of cancer. Ex. F, EPA Off. of Prevention, Pesticides, and Toxic Substances, Alkyl Amine Polyalkoxylates (JITF CST 4 Inert Ingredients): Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations at 4–7, 15–16, 31 (April 3, 2009).

[4] EPA's longstanding conclusion that glyphosate is not carcinogenic in humans—including its 1991 classification—is based on studies and assessments dating back at least to the early 1980s. *See* Ex. H, EPA, Glyphosate: Reregistration Eligibility Decision (RED) Document at 13–14 (Sept. 1993) (animal studies, including studies conducted in 1981, 1983, and 1985, did not support the conclusion that glyphosate was carcinogenic); Ex. I, EPA, Health Effects Division Carcinogenicity Peer Review Committee, Second Peer Review of Glyphosate at 1, 4 (Oct. 30, 1991) (concluding there was a "lack of convincing carcinogenicity evidence" after reviewing, *inter alia*, a 1986 FIFRA Scientific Advisory Panel report and animal studies dating back to 1981).

- In 2004, EPA concluded that glyphosate "has no carcinogenic potential." Final Rule: Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004).

- In 2008, EPA concluded that "[t]here is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant." Final Rule: Glyphosate, Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

- In 2013, EPA reiterated its conclusion that "glyphosate does not pose a cancer risk to humans." Final Rule: Glyphosate; Pesticide Tolerances, 78 Fed. Reg. 25,396, 25,398 (May 1, 2013).

- In 2016, EPA's Office of Pesticide Programs issued a 227-page evaluation of glyphosate's carcinogenic potential, concluding that "[t]he strongest support is for [the descriptor] 'not likely to be carcinogenic to humans' at doses relevant to human health risk assessment." Ex. J, EPA Off. of Pesticide Programs, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential at 141 (Sept. 12, 2016).

- In December 2017, following a notice-and-comment period and an independent review by the EPA Scientific Advisory Panel, EPA's Office of Pesticide Programs confirmed its September 2016 findings and again classified glyphosate as "Not Likely to be Carcinogenic to Humans." Ex. K, EPA, Off. of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential at 144 (Dec. 12, 2017).

- In April 2019, after reviewing "[a]ll studies of adequate scientific caliber that [EPA] was aware of," EPA again concluded that it has "not identif[ied] any human health risks from exposure to any use of glyphosate." Ex. E, EPA, Glyphosate Proposed Interim Registration Review Decision at 7–8, 10.

Virtually every other national and international agency charged with reviewing and approving pesticides agrees with EPA, concluding that the available science does not show that glyphosate causes cancer in humans. Regulators reaching that conclusion include the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan. Ex. A, EPA Letter at 1. Despite this broad consensus on the safety of glyphosate, one agency within the World Health Organization—the International Agency for Research on Cancer ("IARC")—issued a report in 2015 classifying glyphosate as a "Group 2A

agent," describing it as "probably carcinogenic to humans." IARC, Some Organophosphate Insecticides and Herbicides: Volume 112 at 398 (2015), https://monographs.iarc.fr/wp-content/uploads/2018/07/mono112.pdf; *see* Compl. ¶¶ 35–51. IARC's classification is not a determination that glyphosate poses an actual cancer risk in the quantities to which people are exposed in the real world; instead, it is a finding that glyphosate is probably capable of causing cancer given a high enough exposure. Even that limited finding has been rejected by EPA and other regulators.

In an August 2019 letter to registrants of glyphosate-based products, EPA confirmed the labeling requirements for such products under FIFRA. EPA noted that it had recently "reexamine[d] the carcinogenic potential of glyphosate and concluded that glyphosate is 'not likely to be carcinogenic to humans.'" Ex. A, EPA Letter at 1. And EPA forcefully rejected IARC's findings, explaining that it "disagrees with IARC's assessment," because "EPA scientists have performed an independent evaluation of the available data since the IARC classification" and have concluded that glyphosate is not carcinogenic. *Id.*[5] Because, in EPA's consistent view, glyphosate is not carcinogenic, a statement on glyphosate-based products warning that glyphosate presents a risk of cancer would be "false and misleading," and as such would render any glyphosate product so-labeled "misbranded pursuant to section 2(q)(1)(A) of FIFRA." *Id.* Consequently, EPA affirmed, pesticide products including such a cancer warning "do not meet the requirements of FIFRA." *Id.*

[5] The August 2019 letter is not the first time EPA rejected the IARC classification. *See* Ex. K, EPA, Off. of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential at 32–33, 146 (considering data and studies on which IARC relied and nonetheless classifying glyphosate as "Not Likely to be Carcinogenic to Humans"); Ex. E, EPA, Glyphosate Proposed Interim Registration Review Decision at 7–8 (outlining numerous flaws in findings of IARC working group and concluding EPA's cancer evaluation of glyphosate was "more robust" and "more transparent" than IARC's).

In 2018, a district court in California reached a similar conclusion under the First Amendment, preliminarily enjoining enforcement of a California requirement for a cancer warning on glyphosate as unconstitutionally compelling speech that is misleading. *See Nat'l Ass'n of Wheat Growers v. Zeise*, 309 F. Supp. 3d 842, 853–54 (E.D. Cal. 2018).

C. Plaintiff's Allegations.

Plaintiff has been diagnosed with malignant fibrous histiocytoma and alleges that his cancer was caused by exposure to Roundup®. Compl. ¶¶ 60–61. Seeking both compensatory and punitive damages, Plaintiff asserts four causes of action: (1) strict liability (design defect), (2) strict liability (failure to warn), (3) negligence, and (4) breach of implied warranties. Underlying all of these claims is the assertion that Roundup® is "unsafe when used in the manner instructed and provided by Defendant," Compl. ¶ 70, *i.e.*, with "minimal warnings" that allegedly do not include "the full and complete risks of Roundup® and glyphosate-containing products," *id.* ¶ 86. Plaintiff's claims are based on the alleged carcinogenicity of glyphosate. *E.g.*, Compl. ¶ 71(f).

LEGAL STANDARD

A Motion for Judgment on the Pleadings under Federal Rule of Civil Procedure 12(c) "provides a means of disposing of cases" when "a judgment on the merits can be achieved by focusing on the content of the competing pleadings." *Perez v. Wells Fargo N.A.*, 774 F.3d 1329, 1336 (11th Cir. 2014). "Judgment on the pleadings is appropriate where there are no material facts in dispute and the moving party is entitled to judgment as a matter of law." *Id.* at 1335. Because a Rule 12(c) motion challenges the legal sufficiency of the complaint, the allegations in the complaint "are presumed to be true," *Horsley v. Feldt*, 304 F.3d 1125, 1131 n.2 (11th Cir. 2002), although the court need not accept as true "conclusory legal allegations," *Andrx Pharm., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1230 n.1 (11th Cir. 2005).

Along with the complaint's well-pleaded factual allegations, the Court may consider judicially noticeable facts. *Hawthorne v. Mac Adjustment, Inc.*, 140 F.3d 1367, 1370 (11th Cir. 1998) (court may "consider[] the substance of the pleadings and any judicially noticed facts"). The "same standard" governs motions to dismiss and motions for judgment on the pleadings. *See Carbone v. Cable News Network, Inc.*, 910 F.3d 1345, 1350 (11th Cir. 2018). Under that standard, courts routinely take judicial notice of government documents. *See Dimanche v. Brown*, 783 F.3d 1204, 1213 n.1 (11th Cir. 2015) ("Absent some reason for mistrust, courts have not hesitated to take judicial notice of agency records and reports."); *Henderson v. Sun Pharm. Indus., Ltd.*, 809 F. Supp. 2d 1373, 1379 n.4 (N.D. Ga. 2011) ("The Court is permitted to take judicial notice of documents made publicly available by a government entity."). In this case, where all that matters is the fact that EPA has made certain determinations, it is uncontroversial to take judicial notice of EPA reports and documents for the "purpose of determining which statements the documents contain." *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 812 n.4 (11th Cir. 2015).[6]

ARGUMENT

I. FIFRA EXPRESSLY PREEMPTS PLAINTIFF'S CLAIMS.

FIFRA is a comprehensive statutory scheme controlling the use, sale, and labeling of pesticides. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437–38 (2005). In a section entitled "Authority of States," FIFRA delineates the respective roles of the federal and state governments in setting standards for labeling and other aspects of pesticide sale and use. 7 U.S.C. § 136v. A

[6] Monsanto's motion for judgment on the pleadings is timely because it is filed "early enough not to delay trial." Fed. R. Civ. P. 12(c). Courts entertain Rule 12(c) motions even when trial is just a few months away. *See, e.g.*, *King v. Akima Glob. Servs., LLC*, 775 F. App'x 617, 620 n.1 (11th Cir. 2019) (motion timely because it was filed "four months before trial"); *Shipley v. Hypercom Corp.*, 2010 WL 11453635, at *5 n.7 (N.D. Ga. Mar. 15, 2010), *report and recommendation adopted*, 2010 WL 11455943 (N.D. Ga. Apr. 29, 2010) (motion timely filed because "no trial date has been set"). Here, no trial date has been set, and the deadline for Plaintiff to serve his general causation expert reports is not until June 1, 2020.

subsection entitled "Uniformity" includes an express preemption provision prohibiting states from "impos[ing] . . . any requirements for labeling or packaging in addition to or different from those required under this Act [*i.e.*, FIFRA]." 7 U.S.C. § 136v(b). The Supreme Court in *Bates* established a two-part test to determine whether a state-law claim is pre-empted by § 136v(b). 544 U.S. at 444. First, state law must impose a "requirement" for "labeling or packaging." Second, this state-law requirement must be "in addition to or different from" a requirement imposed under FIFRA. *Id.* Because the asserted state-law requirements underlying Plaintiff's claims satisfy both parts of this test, those claims are expressly preempted.

A. Plaintiff's Claims Are Based on State-Law Labeling Requirements.

Plaintiff's claims for damages are based on Georgia common-law duties. In *Bates*, the Supreme Court held that "common-law duties," and not just statutes and regulations, are state-law "requirements" subject to FIFRA's express preemption provision. 544 U.S. at 434; *see also Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993) ("Common law damages awards are . . . 'requirements'" under FIFRA); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (the term "requirement" includes common-law claims, even when the "remedy is limited to damages").

The common-law "requirements" on which Plaintiff's claims are based are "for labeling or packaging." A state-law duty is a "requirement for labeling or packaging" if it "set[s] a standard for a product's labeling that [defendant's] label is alleged to have violated by containing false statements and inadequate warnings." *Bates*, 544 U.S. at 446. Though Plaintiff pleads four causes of action, they all purport to set a standard for Roundup®'s labeling—*i.e.*, to require a warning that the product is carcinogenic. The complaint makes plain that this lack of a warning is the sole cause of Plaintiff's harm and the linchpin of his entire case: "Had Defendant provided adequate warnings . . . Plaintiff could have avoided the risk of developing injuries as alleged herein."

Compl. ¶ 100; *see also id.* ¶ 95 (adequate warnings "would have enabled horticultural workers such as Plaintiff to utilize the products safely and with adequate protection").

For example, Plaintiff's design defect cause of action claims that Roundup® is defectively designed because it is "labeled" in an "inherently dangerous" fashion, Compl. ¶ 66, rendering the product unsafe "when used in the manner instructed and provided by Defendant," *id.* ¶ 70; *see id.* ¶ 79 (alleging, under the heading of the design defect claim, that Monsanto failed to "warn" the "unsuspecting public" about "problems" associated with glyphosate).[7]

Plaintiff's failure-to-warn claim likewise seeks to impose liability for Monsanto's purported failure to include a cancer warning on Roundup®'s label. Compl. ¶ 83. Plaintiff then reiterates the same allegation (that Monsanto failed to warn of glyphosate's purported dangers) and seeks to enforce the same labeling "requirement" (that state law requires a cancer warning) in

[7] Because warnings "are part of the total design package of the product," *Boyce v. Gregory Poole Equip. Co.*, 605 S.E.2d 384, 390 (Ga. App. Ct. 2004), one "theory of defective design" under Georgia law is that a defendant failed to provide adequate warnings, *see Jones v. NordicTrack, Inc.*, 550 S.E.2d 101, 102 n.3 (Ga. 2011). Plaintiff does not appear to be making a claim that the product is defectively designed because it is so "inherently dangerous" that it should not have been made available at all. That would be incompatible with Plaintiff's allegation that warnings would have enabled him "to utilize the products safely." Compl. ¶ 95; *see also id.* ¶ 75 (alleging that Roundup® is unsafe "when used *in the manner instructed and provided* by Defendant" (emphasis added)). But even if Plaintiff intended to make such a claim, such a design defect theory is "extreme," *Banks v. ICI Americas, Inc.*, 264 Ga. 732, 736 (1994), and is subject to dismissal when the facts necessary to support that extreme theory are not pled. *See Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1359 (N.D. Ga. 2016). To the extent Plaintiff means to allege that Roundup® was defectively designed solely because its active ingredient is glyphosate (and not because Roundup® purportedly lacked a warning), the claim also is plainly insufficient—Plaintiff "fail[s] to allege any facts that would enable" a comparison of the risks inherent in Roundup®'s design and the product's benefits under Georgia's risk-utility test. *Brown v. Sirchie Acquisition Co., LLC*, 2017 WL 4082690, at *4–5 (N.D. Ga. Feb. 17, 2017), *aff'd*, 694 F. App'x 745 (11th Cir. 2017) (dismissing complaint because it "contains no facts about reasonable alternative designs, nor does it include anything that relates to the utility of the [product]"). Such a design defect theory also fails because it seeks to hold Monsanto liable for not developing a completely different, non-glyphosate-based product. *See Chambers v. Boehringer Ingelheim Pharm., Inc.*, 2018 WL 849081, at *13 (M.D. Ga. Jan. 2, 2018) (rejecting notion that "failure to timely develop one drug [is] a cognizable design defect claim for another drug").

the subsequent causes of action for negligence and breach of implied warranties. *Id.* ¶¶ 105–106 (alleging negligence because Roundup® lacks "accurate warnings" concerning "the carcinogenic properties of the chemical glyphosate"); *id.* ¶ 120 (alleging breach of implied warranties for "fail[ure] to disclose that Roundup® has dangerous propensities").

In short, Plaintiff's fundamental complaint is that Roundup® should have included a warning that glyphosate is carcinogenic. And as Plaintiff emphasizes throughout, that warning should, in his view, have been delivered as part of Roundup®'s labeling. Because all of Plaintiff's claims "require[] that manufacturers label or package their products in any particular way," they are subject to FIFRA's express preemption provision.

B. The Purported State-Law Requirement to Warn That Glyphosate Is Carcinogenic Is "In Addition to" and "Different from" Federal Labeling Requirements Imposed by FIFRA.

Plaintiff's claims are expressly preempted because the state-law "requirement for labeling or packaging" it seeks to enforce is "in addition to or different from" federal requirements imposed under FIFRA. *See* 7 U.S.C. § 136v(b).

In general, EPA's approval of a label in the course of registering and re-registering a product compels the use of that approved label, without deviation. *See* 7 U.S.C. § 136j(a); 40 C.F.R. § 152.44. And EPA will not approve labeling unless it "has determined that the product is not misbranded as that term is defined in FIFRA . . . , and its labeling and packaging comply with the applicable requirements of the Act." 40 C.F.R. § 152.112(f).

Here, EPA has approved a label for Roundup® with no cancer warning. That approval is based on decades of findings that glyphosate poses no cancer risk to humans, with EPA consistently and definitively determining that no cancer warning is appropriate. *See* Ex. B, U.S. Br. at 13–14 ("EPA has never required a labeling warning of a cancer risk posed by Roundup, and such a warning would be inconsistent with the agency's scientific assessments of the carcinogenic

potential of the product."). By virtue of EPA's authoritative determinations in exercise of its delegated authority, it is a requirement under FIFRA to use the EPA-approved label for glyphosate products—*i.e.*, one with no cancer warning. EPA underscored that requirement just this past August, when it issued a letter to registrants of glyphosate products expressly notifying them that it would not approve such a warning. A state-law requirement to include a warning that deviates from the EPA-approved label and contradicts EPA's scientific judgments underlying its registration decisions—indeed, a warning that EPA has expressly said it would not allow—is "in addition to" and "different from" the labeling requirement imposed by EPA under FIFRA.

Indeed, the purported state-law duty here contradicts FIFRA's requirement that no person may "distribute or sell . . . any pesticide which is adulterated or *misbranded*." 7 U.S.C. § 136j(1)(E) (emphasis added). Under FIFRA, "[a] pesticide is misbranded if its labeling bears any statement . . . which is false or misleading in any particular," *id.* § 136(q)(1)(A), and anyone who sells a misbranded product faces criminal or civil penalties, *see id.* § 136l(a)–(b). EPA in its August 2019 letter squarely confirmed that glyphosate products whose labeling contains a cancer warning are "misbranded pursuant to section 2(q)(1)(A) of FIFRA [7 U.S.C. § 136(q)(1)(A)] and as such do not meet the requirements of FIFRA." Ex. A, EPA Letter at 1. *See also* Ex. B, U.S. Br. at 10 (cancer warning on glyphosate products "constituted prohibited misbranding"); *id.* at 18 (a state-law requirement of a "glyphosate cancer warning on a Roundup label" would "not only require[] a different label (a requirement preempted by FIFRA)" but "would almost certainly compel Monsanto to produce a misleading label warning very much at odds with EPA's scientific assessment of the carcinogenic potential of glyphosate").

Application of preemption on the undisputed facts here is confirmed by the Supreme Court's decision in *Bates*. In *Bates*, the Court held that a claim based on a "state-law labeling

requirement" that differs from what FIFRA requires cannot "survive preemption," but a state-law claim that merely "seeks to enforce" what federal law requires may proceed. 544 U.S. at 447, 453. Thus, a state-law claim could survive preemption if it were "equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447. But equivalence is a demanding requirement—for instance, if state law requires a pesticide's label to say "DANGER" where EPA decides it should include "the more subdued 'CAUTION,'" the state-law requirement "would be pre-empted." *Id.* at 453. Here, of course, the difference between the state and federal law requirements is even greater than "DANGER" versus "CAUTION"; state law, in Plaintiff's view, requires a warning that glyphosate is carcinogenic, which EPA has determined would be false.

On the specific facts of *Bates*, the Court remanded without determining whether or not the state law claims at issue were truly equivalent to federal requirements. And critically, *Bates* involved a challenge to claims made on a label concerning a pesticide's efficacy, rather than its safety—and, as the Court emphasized, EPA had waived its review of all such efficacy-related label claims. *See id.* at 440, 450. Thus, EPA had never vetted or approved the statements on the label at issue in that case.

Here, by contrast, EPA has repeatedly considered—and rejected—the warning that state law purportedly requires. When registering (and re-registering) Roundup®, EPA considered the product's safety and concluded that absence of a cancer warning does not render it misbranded. To the contrary, the *inclusion* of such a warning would make Roundup® misbranded. As the United States has explained in no uncertain terms, "FIFRA does not require a warning on Roundup's label that glyphosate causes cancer." Ex. B, U.S. Br. at 19. Because Plaintiff attempts to enforce a state-law duty that *does* require a cancer warning on that label, his claims are preempted.

This case is analogous to *Riegel*, which concerned a preemption provision that is (as the *Bates* Court recognized) materially identical to FIFRA's preemption provision. *See* 544 U.S. at 447–48. In *Riegel*, plaintiffs challenged the safety and effectiveness of a medical device, despite the fact that the Food and Drug Administration ("FDA") had reviewed the product's safety in granting it premarket approval. The state-law claims were preempted, the court explained, because they differed from the relevant federal requirements—which were established when the FDA determined the device was safe, approved it for sale, and generally barred changes to its configuration or labeling without FDA approval. *See* 552 U.S. at 319. The court in *Riegel* distinguished its decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), where it had concluded that a state-tort suit was not preempted because the agency had not reviewed the device for effectiveness and safety (but had instead approved it via an alternative pathway). 518 U.S. at 493. In this respect, *Lohr* is analogous to *Bates*, in which EPA had not reviewed the pesticide or its labeling for any claims concerning efficacy. Here, by contrast, EPA has frequently examined glyphosate's effects on human health and has determined that no cancer warning is appropriate. As in *Riegel*, EPA's approval triggers specific and mandatory federal labeling requirements that preempt any additional or different state-law requirements. *See* Ex. B, U.S. Br. at 1–2 ("Every time EPA reviews and approves [a pesticide's] label," EPA is "making federal law" that is "tailored" to that particular pesticide).

In sum, there cannot be a clearer example of a state-law requirement "different from" and "in addition to" FIFRA's requirements than a claim, like Plaintiff's here, that would require the defendant to take action directly contrary to the requirements of FIFRA and position of EPA. This Court should thus hold that Plaintiff's claims are expressly preempted.

II. PLAINTIFF'S CLAIMS ARE BARRED BY IMPOSSIBILITY PREEMPTION.

Plaintiff's claims also are barred under impossibility preemption, which preempts state law "where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 473 (2013) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). Impossibility preemption applies here because there is "clear evidence" that EPA would reject any attempt to add a cancer warning to Roundup®'s labeling, and Monsanto is unable to comply with the alleged state-law warning requirement without EPA's prior approval.

A. Plaintiff's Claims Are Barred by Impossibility Preemption Because There Is "Clear Evidence" EPA Would Not Approve the Warning Plaintiff Seeks.

Plaintiff's claims are barred by impossibility preemption because there is "clear evidence" that EPA would exercise its authority to reject any attempt to add a cancer warning to Roundup®'s labeling. The Supreme Court established this "clear evidence" standard in *Wyeth v. Levine*, 555 U.S. 555 (2009), where the Court considered whether it was impossible for a brand-name drug manufacturer to comply with both a state-law duty to warn and federal labeling law. *Id.* at 563. Under the relevant statutory scheme, the manufacturer did have a way to unilaterally effect a labeling change, but the Court held that impossibility preemption would nonetheless apply if there was "clear evidence" the agency would refuse to approve the new warning. *Id*. at 571–72. Last year, the Court clarified this "clear evidence" standard in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). "Clear evidence" exists, the Court said, if the relevant federal agency was "fully informed" of the "justifications for the warning" the plaintiff demands, and that agency nonetheless determined that it would not approve such a warning. *Id.* at 1676, 1678. Both prongs of this "clear evidence" test are met here.[8]

[8] Despite the Supreme Court's use of the term "evidence," the Court has made clear that whether "clear evidence" exists that an agency would reject a proposed labeling change is "a question of law, normally for a judge to decide without a jury." *Albrecht*, 139 S. Ct. at 1679.

First, EPA itself has confirmed that it is "fully informed" of the evidence purporting to show that glyphosate is carcinogenic. The agency repeatedly has undertaken in-depth scientific reviews of the evidence on glyphosate's safety, concluding it is safe and non-carcinogenic. Each of these determinations was based on an extensive review of scientific evidence. The most recent determinations include a 227-page evaluation of glyphosate's carcinogenic potential, released in 2016, and a further review, released in 2019, of "[a]ll studies of adequate scientific caliber that [EPA] was aware of." Ex. E, EPA, Glyphosate Proposed Interim Registration Review Decision at 7–8, 10. These most recent determinations were made *after* the IARC report cited in the complaint was made public and specifically addressed both the data relied upon by IARC and IARC's findings. *See supra* pp. 11–12. Indeed, when concluding that glyphosate is not carcinogenic, EPA specifically noted that its review of the scientific literature was more robust, because "IARC only considered a subset of the studies included in the EPA's evaluation." Ex. E, EPA, Glyphosate Proposed Interim Registration Review Decision at 7. In its August 2019 letter, the agency again confirmed that "EPA scientists have performed an independent evaluation of available data," and that it "considered a more extensive dataset than IARC." Ex. A, EPA Letter at 1. It is beyond dispute that EPA was "fully informed."

Second, EPA's consistent findings that glyphosate poses no cancer risk to humans, and its consequent determinations (in the course of formal registration decisions) that no cancer warning is warranted, constitute clear evidence that the agency would not approve a request to add a cancer warning. EPA made that explicit in its August 2019 letter, where EPA informed glyphosate registrants that it would not approve such a warning. But EPA's recent letter simply confirms what has been true for almost three decades: EPA does not believe glyphosate is a carcinogen, it views a cancer warning in these circumstances as false and misleading, and it "would not approve

a change to the [product's] label to include" a cancer warning because that would constitute misbranding under FIFRA and its implementing regulations. *Albrecht*, 139 S. Ct. at 1672. EPA would reject any attempt to add a cancer warning to Roundup®'s labeling.

B. Plaintiff's Claim Is Barred by Impossibility Preemption Because Monsanto Cannot Alter Roundup®'s EPA-Approved Labeling.

Even apart from the *Wyeth*/*Albrecht* "clear evidence" standard, impossibility preemption also bars Plaintiff's claims because Monsanto cannot add a cancer warning to Roundup®'s label without EPA's approval—such that Monsanto cannot "independently do under federal law what state law requires of it." *PLIVA Inc. v. Mensing*, 564 U.S. 604, 620 (2011).

In *Mensing*, the Supreme Court held that a state-law failure-to-warn claim is preempted if federal law does not allow a defendant to enact the labeling change that state law purportedly requires—here, adding a cancer warning to Roundup®'s label—without prior approval from the federal government. *See* 564 U.S. at 615–18. In that case, generic drug manufacturers argued it was "impossible" for them to add a warning required by a state-law tort suit because federal law required them to use the exact same label that FDA has approved for the equivalent brand-name drug. *Id.* at 617. The Court agreed and further clarified that whether the manufacturers could have convinced FDA to permit the label change is irrelevant; impossibility preemption applied because the manufacturers "would have violated federal law" if they "had independently changed their labels to satisfy their state-law duty." *Id.* at 618.

The same is true here. Unlike the brand-name drug manufacturers in *Wyeth*, pesticide manufacturers like Monsanto cannot unilaterally add a cancer warning to their product's labeling. To change a pesticide's labeling, the manufacturer must submit to EPA an amended registration application—that is, a formal request that the agency re-register the pesticide, along with all data that is relevant to the proposed change—and EPA must approve the proposed change before the

revised label may be used. 40 C.F.R. §§ 152.44(a), 152.50.[9] Because Monsanto cannot independently change Roundup®'s labeling, all of Plaintiff's claims are preempted.

CONCLUSION

For the foregoing reasons, this Court should grant Defendant's motion for judgment on the pleadings under Fed. R. Civ. P. 12(c) and dismiss the complaint with prejudice.

Dated: January 15, 2020

Respectfully submitted,

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[9] Although a pesticide manufacturer may make certain changes to the label via "notification" or, in some cases, without any notification at all, *see* 40 C.F.R. § 152.46; Ex. L, EPA, Office of Pesticide Programs, Pesticide Registration Notice 98-10 at 2–14 (Oct. 22, 1998) ("Notice 98-10"), that streamlined process is limited to "minor" modifications, Notice 98-10 at 1, not substantive changes like the addition of a cancer warning.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 15th day of January, 2020, a copy of the foregoing was filed with the Clerk of the Court through the CM/ECF system, which will generate an electronic notification and effect service on all counsel of record.

/s/ Martin C. Calhoun

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