No. 21-10994

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

JOHN D. CARSON,
Plaintiff-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellee,

On Appeal from the United States District Court
for the Southern District of Georgia
No. 4:17-cv-00237-RSB-CLR (Baker, J.)

BRIEF OF DEFENDANT-APPELLEE MONSANTO COMPANY

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CERTIFICATE OF INTERESTED PARTIES

Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rule 26.1-1(a)(3), Appellee Monsanto Company, through undersigned counsel, hereby submits this Certificate of Interested Persons and Corporate Disclosure Statement.

Below is a complete list of all trial judges, attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of the particular case or appeal, including subsidiaries, conglomerates, affiliates, part corporations, any publicly held corporations that owns 10% or more of the party's stock, and other identifiable legal entities related to a party:

Interested Persons

1. Baker, Hon. R. Stan, United States District Judge
2. Boswell, Chase E., Attorney for Appellee (in the district court)
3. Calhoun, Martin C., Attorney for Appellee
4. Carson, John D., Sr., Appellant
5. Hollingsworth, Joe G., Attorney for Appellee
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8. Madison, Ashleigh Ruth, Attorney for Appellant
9. Marshall, K. Lee, Attorney for Appellee

10. Ray, Hon. Christopher L., United States Magistrate Judge

11. Thomas, Michael J., Attorney for Appellee (in the district court)

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Entities

14. Bayer AG, BAYRY

15. Bryan Cave Leighton Paisner LLP

16. Covington & Burling LLP

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18. Monsanto Company

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Dated: June 4, 2021

Respectfully submitted,

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STATEMENT REGARDING ORAL ARGUMENT

Defendant-Appellee Monsanto Company respectfully requests oral argument pursuant to 11th Cir. R. 28-1(c). Oral argument is warranted because this appeal presents an issue of first impression in this Circuit: Whether the Federal Insecticide, Fungicide, and Rodenticide Act preempts a state-law failure-to-warn claim for a pesticide where the Environmental Protection Agency has repeatedly determined that the proposed warning is contrary to the scientific evidence and thus false.

This case is one of thousands in which a plaintiff has alleged that Monsanto violated state law by failing to warn that exposure to glyphosate, the active ingredient in the herbicide Roundup®, could cause cancer, even though EPA has repeatedly determined that glyphosate is not likely to be carcinogenic to humans, has authorized Roundup® for sale, has approved Roundup®'s labeling, and has concluded that a cancer warning would make glyphosate-based products, such as Roundup®, misbranded. The Ninth Circuit recently issued a decision concluding that preemption does not apply, with which Monsanto respectfully disagrees. Oral argument will illuminate the parties' positions and aid the Court in reaching a decision in this case.

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GLOSSARY

1993 Reregistration Eligibility Decision	EPA, Reregistration Eligibility Decision (RED) – Glyphosate (Sept. 1993)
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
Hardeman U.S. Br.	Br. of United States as Amicus Curiae in Support of Monsanto, *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir.)
IARC	International Agency for Research on Cancer
Interim Registration Review Decision	EPA, Glyphosate: Interim Registration Review Decision Case No. 0178 (Jan. 2020)
Letter to Registrants	EPA, Office of Pesticide Programs, Letter to Glyphosate Registrants Regarding Labeling Requirements (Aug. 7, 2019)
MDA	Medical Device Amendments of 1976
NRDC EPA Br.	Brief of the U.S. EPA, *NRDC v. EPA*, Nos. 20-70787, 20-70801, Dkt. 80 (9th Cir. May 18, 2021)

INTRODUCTION

According to the Environmental Protection Agency ("EPA"), glyphosate—the world's most widely used herbicide—does not cause cancer. That is the formal conclusion of an expert federal agency exercising congressionally-delegated authority. Pursuant to its responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), EPA has for decades studied the extensive body of science on glyphosate, and reiterated its determination that glyphosate is not carcinogenic. EPA has repeatedly reached that conclusion as part of a formal regulatory procedure prescribed by Congress. It has subjected that determination to the scrutiny of public notice and comment. It has specifically notified registrants of glyphosate products that any warning that glyphosate causes cancer would be false, would make their products misbranded in violation of FIFRA, and would therefore be rejected by EPA in its statutory control over pesticide labeling. And in May 2021, EPA completed an Executive Order review of the agency's latest regulatory action on glyphosate, and vigorously defended the agency's "conclu[sion] that glyphosate is not likely to be a human carcinogen and poses no human-health risks of concern." Br. of the U.S. EPA 1, *Nat'l Res. Def. Council v. U.S. Env't Prot. Agency* (*NRDC v. EPA*), Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021) ("*NRDC* EPA Br.").

But according to Plaintiff, Georgia common law requires the exact warning that EPA rejects. In his view, Monsanto is liable under state law for failing to warn that glyphosate, the active ingredient in its Roundup® brand herbicide products,

causes cancer. The fundamental problem with this claim is that, as a result of EPA's formal determination that glyphosate does not cause cancer, FIFRA forbids such a warning: it would deviate from Roundup®'s approved labeling, it would render Roundup® misbranded, and it would require Monsanto to make a label change that EPA could not and would not approve. Mandating such a warning under pain of civil damages unmistakably imposes a labeling requirement that is "different from or in addition to" federal requirements, and thus runs afoul of FIFRA's preemption provision. 7 U.S.C. §136v(b). Likewise, EPA's exacting review of glyphosate's potential cancer risk across six presidential administrations makes it clear that EPA has been fully informed of the relevant evidence and would reject any effort to add the allegedly necessary warning—making Plaintiff's claim barred by impossibility preemption under recent Supreme Court precedent as well.

This case is one of thousands of personal injury actions seeking to hold Monsanto liable for not changing the Roundup® labeling to include a warning that EPA has decided is false. The district court correctly dismissed Plaintiff's failure-to-warn claim as preempted by federal law. Other courts have reached different conclusions, however, and after Plaintiff filed his opening brief, the Ninth Circuit decided the first federal Roundup® appeal. *See Hardeman v. Monsanto Co.*, __ F.3d __, Nos. 19-16636, 19-16708, 2021 WL 1940550 (9th Cir. May 14, 2021). Though *Hardeman* recognized that "EPA has repeatedly approved the use of glyphosate as

a pesticide, each time concluding that it is not likely to be carcinogenic to humans," the Ninth Circuit held that FIFRA does not preempt a state-law requirement to warn of a risk EPA has "conclud[ed]" does not exist. *Id.* at *3, 7-8. That decision cannot be squared with FIFRA's mandate and Supreme Court precedent, and this Court should not follow it. EPA's regulatory actions determining that glyphosate does not cause cancer and that, accordingly, no cancer warning is warranted, taken pursuant to a detailed statutory process and following notice-and-comment procedures, have the force of law and, in any event, are far *more* formal than agency actions that the Supreme Court treats as having preemptive effect. Nothing in FIFRA or any preemption case requires this Court to blind itself to the reality that EPA has decided that glyphosate products should not carry a cancer warning, and that Monsanto cannot comply with a state-law requirement to add such a warning without landing in federal jeopardy.

This Court should affirm the district court's dismissal and hold that Plaintiff's failure-to-warn claim is preempted by federal law. Any other outcome would subject Monsanto to civil damages, thousands of times over, for not adopting a warning that the Congressionally-delegated expert federal agency has decided is scientifically inaccurate and is therefore false.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. §1332 because Plaintiff-Appellant Dr. John D. Carson, Sr. and Defendant-Appellee Monsanto Company are

citizens of different states and the amount in controversy exceeds $75,000. On December 21, 2020, the district court entered an order dismissing some, but not all, of Plaintiff's claims, including his failure-to-warn claim. App. 89-104. On March 22, 2021, the district court granted Plaintiff's motion to amend his complaint in order to dismiss his remaining claims (while preserving his right to appeal the dismissal of his failure-to-warn claim), and directed the Clerk of the Court to enter final judgment in favor of Monsanto. App. 106. The Clerk entered final judgment on March 30, 2021. Supp. App. 434. Plaintiff filed a notice of appeal on March 26, 2021. App. 108. Pursuant to Federal Rule of Appellate Procedure 4(a)(2), that notice of appeal "is treated as filed on the date of and after the entry" of final judgment. *Id.*; *see also, e.g.*, *QBE Specialty Ins. Co. v. Scrap Inc.*, 806 F. App'x 692, 695 n.1 (11th Cir. 2020). This Court has appellate jurisdiction under 28 U.S.C. §1291.[1]

RELEVANT STATUTES AND REGULATIONS

Pursuant to Rule 28(f), relevant statutes and regulations are reproduced in the Addendum to this brief.

[1] As Monsanto has explained, the parties reached a settlement under which the amount of Plaintiff's recovery is contingent on resolution of this appeal. This Court's jurisdiction following that settlement is explained in Monsanto's Opposition to the Motion by Non-Parties For "Leave to File Letter Brief."

ISSUE ON APPEAL

Whether the district court correctly dismissed Plaintiff's state-law failure-to-warn claim, which alleges that Monsanto should have provided a warning on its pesticide Roundup® that glyphosate causes cancer despite EPA's determination that glyphosate does not cause cancer, because the claim is preempted by FIFRA, 7 U.S.C. §136 *et seq*.

STATEMENT OF THE CASE

Monsanto has manufactured Roundup®, a line of products for which glyphosate, a broad-spectrum herbicide, is the active ingredient.[2] For decades, EPA has exercised its authority under FIFRA to approve glyphosate and glyphosate-based herbicides such as Roundup®, and in discharging its delegated responsibilities under FIFRA has consistently determined that glyphosate is not carcinogenic. This case is one of thousands seeking to hold Monsanto liable under state law for failing to warn that glyphosate causes cancer, notwithstanding EPA's conclusion to the contrary. The district court dismissed that claim as preempted by FIFRA.

A. Statutory and Regulatory Background

FIFRA is a "comprehensive regulatory statute." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)). It requires EPA to regulate "the use, … sale[,] and labeling[] of pesticides." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437 (2005)

[2] FIFRA treats herbicides, which target unwanted vegetation, as pesticides that must be registered with the EPA. *See* 7 U.S.C. §136(t), (u); 40 C.F.R. §152.15.

(quoting *Ruckelshaus*, 467 U.S. 986, 992 (1984)); *see* 7 U.S.C. §136 *et seq*. For EPA to register a pesticide for sale in the United States, it must first "determine that the pesticide will not cause 'unreasonable adverse effects on the environment,'" *id.* at 992 (quoting 7 U.S.C. §136a(c)(5)(C)), which includes no unreasonable adverse effects on human health, 7 U.S.C. §136(bb). As part of that assessment, "EPA reviews pesticides for potential carcinogenicity," and the resulting cancer "classification will determine how the Agency regulates the pesticide." EPA, *Evaluating Pesticides for Carcinogenic Potential*, https://tinyurl.com/ujj76j53 (last visited June 4, 2021). Among other things, if the agency concludes that a pesticide is carcinogenic, it will consider a restricted use classification for the product. 40 C.F.R. § 152.170(b)(vi). EPA makes registration determinations only after analyzing voluminous scientific data and information. *See* 7 U.S.C. §§136a(c)(1)(F), (2)(A); 40 C.F.R. §158.500.

FIFRA also requires EPA to review a pesticide's registration, including its effects on human health, at least once every fifteen years. 7 U.S.C. §136a(g)(1)(A)(i), (iv). These reviews are extensive and often span many years. *See* EPA, *Registration Review Process*, https://tinyurl.com/27u38c5t (last visited June 4, 2021). In carrying out this review, EPA may release its evaluations as they are completed, using "interim" decisions to finalize parts of a registration. In reaching "interim" registration review decisions, EPA follows the same formal procedures for

issuing completed registration review decisions. *See* 40 C.F.R. §§155.56, 155.58; *see also NRDC* EPA Br. 14 (explaining that "the Interim Decision finalized the draft human-health and ecological risk assessments" for the glyphosate registration review).

As part of FIFRA's registration and registration review processes, EPA must approve a pesticide's label, which the manufacturer then must use without modification. 7 U.S.C. §136j(a)(1)(E). Based on its safety assessment, EPA may require a pesticide's labeling to feature "human hazard" or "precautionary statements" to convey warnings about potential health risks and mitigation actions, 40 C.F.R. §§156.60-156.70; mandatory personal protective equipment, *id.* §156.212; detailed application directions to protect human health and safety, *id.* §156.10(i)(1), (2); or designations for use restricted to "certified applicators" based on possible health, safety, or other risks it identifies, 7 U.S.C. §136a(d); 40 C.F.R. §156.10(j). And if EPA classifies a pesticide for restricted use based on carcinogenicity, specific regulatory labeling requirements apply. *See* 40 C.F.R. §156.10(j)(2), §152.166(a); EPA, Pesticide Regulation Notice (PR) 93-1: Statement of Restricted Use Classification (Feb. 11, 1993), https://tinyurl.com/n7v5bmhc (instructing that products not classified for restricted use should be labeled differently).

FIFRA prohibits labeling and packaging that is "misbranded," meaning that pesticide labels must contain adequate instructions for use; must include any "warning or caution statement which may be necessary … to protect health and the environment"; and must not be "false or misleading in any particular." 7 U.S.C. §136(q)(1)(A), (F), (G); *id.* §136a(c)(5)(B); 40 C.F.R. §156.10(a)(5)(ii). It is unlawful for any person to distribute or sell the pesticide "if any claims made for it as part of its distribution or sale substantially differ" from its approved labeling. 7 U.S.C. §§136j(a)(1)(B); *see also id.* §136j(a)(2)(G).

EPA exercises control over any change to the approved labeling, including to ensure that such changes do not violate FIFRA's requirements. Every change save for "minor modifications" requires a new application which EPA must approve. 40 C.F.R. §§152.44, 152.46. Thus, registrants are prohibited from adding a new "health hazard" to the "precautionary statement" portion of the label or changing the formulation of the pesticide without first obtaining EPA's approval. *See* EPA, Pesticide Registration Notice (PR) 98-10: Notifications, Non-Notifications and Minor Formulation Amendments at 8 (Oct. 22, 1998), https://tinyurl.com/y6e5zxp7 (change to "precautionary statements" does not qualify as "[m]inor label change"). Even where EPA permits a label change without prior approval, it may "initiate regulatory or enforcement action" if the agency "determines" that the change was not consistent with "applicable law or regulations." *Id.* at 19.

FIFRA includes an express preemption provision. Titled "Uniformity," it provides that a state may "not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. §136v(b). As the Supreme Court has held, only state-law requirements that are "parallel" to federal law may survive preemption under §136v(b); if a state labeling requirement is not "*genuinely* equivalent" to a federal labeling requirement, it is preempted. *Bates*, 544 U.S. at 447, 454 (emphasis in original).

B. EPA's Consistent Determinations That Glyphosate Does Not Pose a Cancer Risk.

EPA first registered glyphosate in 1974, and for nearly fifty years, EPA has continually evaluated the relevant scientific evidence. EPA has repeatedly approved the use of glyphosate as a pesticide, each time concluding that it does not cause unreasonable adverse effects on human health, and that it is not likely to be carcinogenic to humans. *See* Supp. App. 395 (EPA, Glyphosate: Interim Registration Review Decision Case No. 0178 (Jan. 2020) ("Interim Registration Review Decision") (reaffirming that glyphosate poses "no risks to human health" and is "not likely to be carcinogenic to humans")).[3]

As part of this ongoing registration and approval process, EPA has extensively examined and reexamined the potential cancer risk of glyphosate. In response to a

[3] As the district court recognized (*see* App. 90 n.2), and Plaintiff does not challenge, EPA documents are judicially noticeable. *See Dimanche v. Brown*, 783 F.3d 1204, 1213 n.1 (11th Cir. 2015).

1983 study that had raised concerns about potential carcinogenicity, EPA conducted a robust re-evaluation of glyphosate's effects on human health as part of its formal re-registration process. EPA considered numerous carcinogenicity studies in rats and mice, and found that none showed "convincing evidence" that glyphosate could be a carcinogen. Supp. App. 083-84 (EPA, Reregistration Eligibility Decision (RED) – Glyphosate (Sept. 1993) ("1993 Reregistration Eligibility Decision"). On that basis, EPA in 1991 "classified glyphosate as a Group E carcinogen," meaning there was "evidence of non-carcinogenicity in humans." *Id.* at 084. EPA has reaffirmed its finding of no cancer risk based upon updated analyses of the scientific record on multiple occasions in the 1990s, 2000s, 2010s, and early 2020s.[4]

In 2015, a working group at the International Agency for Research on Cancer ("IARC"), an agency of the World Health Organization, issued a report classifying glyphosate as a "Group 2A" agent, meaning it is "probably carcinogenic to humans,"

[4] *See* Supp. App. 165 (EPA, Health Effects Division, Second Peer Review of Glyphosate (Oct. 30, 1991)); Supp. App. 069 (1993 Reregistration Eligibility Decision); EPA, Report of the Hazard Identification Assessment Review Committee at 6-7 (Apr. 20, 1998), https://tinyurl.com/b95mdvja; Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002); Final Rule: Glyphosate, Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008); EPA, Office of Pesticide Programs, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential at 141 (Sept. 12, 2016), https://tinyurl.com/4d6us439; Supp. App. 311 (EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017)); Supp. App. 056-057 (EPA, Glyphosate – Proposed Interim Registration Review Decision Case Number 0178 (Apr. 2019)); Supp. App. 395 (Interim Registration Review Decision).

based on "limited" evidence of cancer in humans and "sufficient" evidence of cancer in experimental animals. IARC, Monograph on Glyphosate at 78 (Mar. 2015), https://tinyurl.com/3uhk7avb. By its own terms, IARC's classification reflects only a hazard assessment, which considers whether an agent is capable of causing cancer under any possible circumstances, without taking into account whether there is some actual risk at real-world levels of human exposure. *See id.* at 75-79.

Meanwhile, as part of its FIFRA-mandated registration review, EPA took another fresh look at glyphosate's potential carcinogenicity, and after an extensive, nearly five-year examination where it re-analyzed all of the available scientific data, EPA reaffirmed its earlier conclusion that glyphosate is non-carcinogenic. As part of that process, which included independent review by an EPA Scientific Advisory Panel, EPA reviewed the studies included in IARC's analysis as well as "additional studies," and "conducted a systematic review of the open literature and toxicological databases for glyphosate." Supp. App. 180 (EPA, Revised Glyphosate Issue Paper (Dec. 12, 2017)). In April 2019, EPA reiterated this conclusion in its Proposed Interim Registration Review for glyphosate, noting that its evaluation was "more robust" and "more transparent" than IARC's, and "consistent with other regulatory authorities and international organizations." Supp. App. 056-57 (EPA, Glyphosate: Proposed Interim Registration Review Decision (Apr. 2019)).

In a letter issued in August 2019, EPA again re-confirmed its determination that glyphosate is "not likely to be carcinogenic to humans." Supp. App. 011 (EPA, Office of Pesticide Programs, Letter to Glyphosate Registrants Regarding Labeling Requirements (Aug. 7, 2019) ("Letter to Registrants")). EPA's letter addressed a California state-law requirement to include cancer warnings on labels of glyphosate products based on the 2015 determination by IARC.[5] EPA explained to glyphosate registrants 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.* Because of that conclusion, a statement on glyphosate-based products warning that glyphosate does present a risk of cancer would be "false and misleading," and would render any product so labeled "misbranded pursuant to section 2(q)(1)(A) [7 U.S.C. §136(q)(1)(A)] of FIFRA." *Id.* Consequently, pesticides including a warning that glyphosate causes cancer "do not meet the requirements of FIFRA." *Id.*

Five months later, after considering the input from an extended notice-and-comment period in which the agency received more than 283,000 comments, EPA issued a final Interim Registration Review Decision for glyphosate. In so doing,

[5] A court has enjoined this California warning requirement as unconstitutional compelled speech, finding that such a warning is "false and misleading given the weight of authority showing that glyphosate was not known to cause cancer and did not cause cancer." *Nat'l Assoc. of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247, 1259, 1266 (E.D. Cal. 2020), *appeal pending*, No. 20-16758 (9th Cir.).

EPA again confirmed that it had "thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." Supp. App. 395 (Interim Registration Review Decision). As a result, while EPA initiated certain interim ecological risk mitigation measures, it did not find that any mitigation measures were necessary to protect human health.

Petitions seeking judicial review of the Interim Registration Review decision are pending in the Ninth Circuit. *See NRDC v. EPA*, Nos. 20-70787, 20-70801 (9th Cir.). Following the change of presidential administration on January 20, 2021 and pursuant to Executive Order, EPA moved to hold the proceedings in abeyance so that it could review the decision; after that review, President Biden's EPA reaffirmed the view espoused by every prior Administration's EPA: "As to human health risks, EPA has reviewed the Interim Decision and believes that this component of its analysis should be sustained." Mot. for Partial Remand Without Vacatur at 17, *NRDC v. EPA*, Dkt. No. 82-1 (9th Cir. May 18, 2021). Concurrently, EPA filed a brief endorsing the "conclu[sion] that glyphosate is not likely to be a human carcinogen and poses no human-health risks of concern," explaining that "[t]he

record underlying these conclusions is robust, reflecting more than a decade of analysis and thorough review of the scientific literature." *NRDC* EPA Br. 1.[6]

Virtually every other national and international agency charged with reviewing and approving pesticides agrees with EPA that the available science does not show that glyphosate causes cancer in humans. 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, among others, all have rejected the position that glyphosate causes cancer. Supp. App. 011 (Letter to Registrants).

C. Procedural History

In December 2017, Dr. John D. Carson, Sr. sued Monsanto, alleging that he applied Roundup® to his lawn routinely for about 30 years and thereafter was diagnosed with a type of cancer (malignant fibrous histiocytoma). *Id.* ¶¶ 60-62. Plaintiff asserted four counts under Georgia law: (1) strict liability design defect, (2) strict liability failure to warn, (3) negligence, and (4) breach of implied warranties,

[6] While EPA's Interim Registration Review Decision is "[not] a registration decision," *NRDC* EPA Br. 1, it does "finalize" the agency's human-health assessment for that registration review, *see id.* at 14. In the pending petitions for review, EPA has not argued that the Interim Decision is not final agency action. The agency's finalized cancer determination is binding, including on all registrants of individual glyphosate products.

primarily asserting that Monsanto should have warned that Roundup® causes cancer. App. 27-43 (Compl. ¶¶ 63-131).

Monsanto moved for judgment on the pleadings. The district court granted that motion in part, dismissing counts 2 (failure to warn) and 4 (breach of implied warranties) as expressly preempted by FIFRA. App. 98. The district court also dismissed in part counts 1 (design defect) and 3 (negligence), concluding that they were preempted "to the extent those claims are based on the labeling or packaging of Roundup," but allowed a narrow theory of potential liability to proceed based on any alleged defects other than inadequate warnings. *Id.*

After the district court's ruling, the parties reached a "high-low" settlement, under which Plaintiff agreed to drop his remaining claims and the amount of his recovery depends on whether this Court affirms or reverses dismissal of his failure-to-warn claim. *See* Monsanto's Opp'n to Mot. By Non-Parties for "Leave to File Letter Br." at 10-11. Following amendment of his complaint to drop his non-warning claims, the district court directed entry of final judgment in favor of Monsanto. App. 106.

SUMMARY OF ARGUMENT

1. Under FIFRA's express preemption provision, states may only impose labeling requirements if they are genuinely equivalent to federal requirements. Here, Plaintiff's failure-to-warn claim is based on a state labeling requirement purportedly requiring Monsanto to include a cancer warning on Roundup's labeling.

FIFRA, however, does not require such a warning—it prohibits it. Pursuant to FIFRA, EPA engages in extensive safety review of a pesticide and decides what warnings may and may not appear on the pesticide's labeling. If after that safety assessment EPA concludes that a particular warning would be false and misleading and would therefore make the product misbranded, the agency cannot approve it, as it would violate FIFRA's requirements. In the case of glyphosate, EPA has repeatedly determined that glyphosate does not cause cancer. As a result, FIFRA requires registrants not to add a cancer warning to a glyphosate product's labeling, and any State law requirement to do so is "in addition to or different from those required under" FIFRA.

The Ninth Circuit, in *Hardeman*, correctly recognized EPA's repeated determination that glyphosate is not a likely human carcinogen. Yet it denied EPA's cancer determination any effect for preemption purposes on the theory that EPA never reached that conclusion in an agency action with the force of law. The "force of law" concept that *Hardeman* borrowed from implied preemption case law is not the proper focus of the express preemption analysis. The question for express preemption purposes is whether FIFRA requires a cancer warning for glyphosate. And under FIFRA and its implementing regulations, the formal registration process is how the agency makes the pesticide-specific decisions that determine how FIFRA's requirements apply to a particular product. The Supreme Court's

interpretation of a nearly identically worded preemption clause in the Medical Device Amendments further compels this conclusion. There, where the agency had approved a device through a premarket approval process that includes safety review, the Supreme Court held that process itself created federal requirements, without any separate analysis of whether the approval has the force of law. The same analysis governs here.

2. Plaintiff's claim is independently barred by impossibility preemption. Monsanto could not have added a cancer warning to the Roundup label over EPA's objection, and there is clear evidence that EPA would have rejected such a warning. First, EPA was fully informed of the supposed basis for a cancer warning—EPA has carefully considered IARC's report and every piece of evidence that Roundup plaintiffs have pointed to as supporting the view that glyphosate causes cancer. Second, EPA has clearly communicated that it would reject a cancer warning. For decades EPA has determined that glyphosate does not cause cancer, making it clear that it would not approve a cancer warning contradicting that determination, and recently EPA expressly confirmed that it would reject such a warning. Finally, EPA's determinations that glyphosate does not cause cancer and that it would not approve a cancer warning have been made as part of formal administrative proceedings that have the force of law. Indeed, EPA's actions concerning glyphosate were far more formal than the agency actions that the Supreme Court, in

Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679 (2019), recognized as carrying the force of law sufficient for impossibility preemption.

STANDARD OF REVIEW

This Court reviews *de novo* an order granting a motion for judgment on the pleadings. *Perez v. Wells Fargo N.A.*, 774 F.3d 1329, 1335 (11th Cir. 2014). "Judgment on the pleadings is proper when no issues of material fact exist, and the moving party is entitled to judgment as a matter of law based on the substance of the pleadings and any judicially noticed facts." *Cunningham v. Dist. Atty.'s Office for Escambia Cnty.*, 592 F.3d 1237, 1255 (11th Cir. 2010).

ARGUMENT

Under the Supremacy Clause, "any state law that interferes with, or is contrary to, federal law is preempted." *Estrada v. Becker*, 917 F.3d 1298, 1302 (11th Cir. 2019) (citation and internal quotation marks omitted). Plaintiff's Georgia law failure-to-warn claim is preempted, both by FIFRA's express preemption provision, 7 U.S.C. §136v(b), and by operation of impossibility preemption.

I. FIFRA Expressly Preempts Plaintiff's State-Law Failure-to-Warn Claim.

To ensure national "Uniformity" of pesticide labeling, FIFRA expressly preempts state laws that "impose … any requirements for labeling or packaging in addition to or different from those required under this subchapter [*i.e.*, under FIFRA]." 7 U.S.C. §136v(b). Plaintiff's state-law failure-to-warn claim is

preempted by §136v(b) because it seeks to enforce a state law requirement for labeling or packaging, and that requirement is different from or in addition to—indeed, it is directly contrary to—federal requirements under FIFRA.

A. Plaintiff's Failure-to-Warn Claim Seeks To Enforce A State-Law Labeling Requirement To Warn That Glyphosate Causes Cancer.

Plaintiff's common-law failure-to-warn claim is based on a "requirement[] for labeling or packaging" under FIFRA. 7 U.S.C. §136v(b). As *Bates* held, "the term 'requirements' in §136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties" that "set a standard for a product's labeling." 544 U.S. at 443, 446. "[P]laintiff's failure to warn claim asserts that Monsanto failed 'to provide adequate warnings or other clinically relevant information and data regarding … the risks associated with' Roundup." App. 95 (quoting Compl. ¶ 98). As the district court correctly recognized, that "most definitely is a requirement for labeling and packaging." *Id.*

Bates refutes Plaintiff's argument that no labeling requirements are involved because he "seeks damages, not injunctive relief." Pl.'s Br. 23. Plaintiff relies on the Supreme Court's discussion of why *design defect* claims were not labeling requirements just because they might "induce the manufacturer to change its label." *Id.* (quoting *Bates*, 544 U.S. at 446). But the *Bates* plaintiffs' failure-to-warn claims—which were "claims for damages"—were "premised on common-law rules that qualify as 'requirements for labeling or packaging.'" *Bates*, 544 U.S. at 434,

446. The Court reiterated this point in *Riegel v. Medtronic*, a case construing the Medical Device Amendments of 1976 ("MDA"), confirming that the statutory term "'requirements' includes [a state's] common-law duties," even if "the common-law remedy is limited to damages." 552 U.S. 312, 324 (2008).

Plaintiff cannot avoid preemption by suggesting that his claim "includes" some unspecified elements that are "not based upon labeling or packaging." Pl.'s Br. 17-18. FIFRA defines "labeling" broadly. It includes the "label" itself, which "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). And it includes "all other written, printed, or graphic matter" that "accompany[] the pesticide at any time," or "to which reference is made on the label or in literature accompanying the pesticide or device" (apart from references to governmental publications). *Id.* §136(p)(2). The Complaint alleges that "Roundup products … do not *contain* adequate warnings or instructions," and that "the minimal warnings [that Monsanto] disseminated *with* its Roundup products were inadequate." App. 31-32, 34 (Compl. ¶¶ 83, 94 (emphasis added)). These alleged deficiencies directly challenge the "written, printed, or graphic matter" that are "on, or attached to" the product, or at least that "accompany" it. 7 U.S.C. §136(p).

Nor can Plaintiff avoid preemption by hypothesizing about "an inadequate point-of-sale warning," Pl.'s Br. 17, which is nowhere mentioned in the Complaint.

Even if the Complaint had alleged anything about point-of-sale warnings, a warning delivered at the "point of sale" would necessarily "accompany[] the pesticide" when it is sold, so it is "labeling" under FIFRA. 7 U.S.C. §136(p)(2). Moreover, FIFRA prohibits pesticide registrants from making any claims that "substantially differ" from claims in the required registration statement, which includes a "complete copy of the labeling of the pesticide." *Id.* §§136j(a)(1)(B), 136a(c)(1). By regulation, "EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access." 40 C.F.R. §168.22. And under this Court's binding precedent, "any claims that point-of-sale signs … failed adequately to warn the plaintiff necessarily challenge the adequacy of the warnings provided on the product's labeling or packaging." *Papas v. Upjohn Co.*, 985 F.2d 516, 519 (11th Cir. 1993).[7]

B. The Alleged State-Law Labeling Requirement Is In Addition To Or Different From Federal Requirements.

A state labeling requirement is "in addition to or different from" a federal labeling requirement unless the state and federal requirements are truly "parallel." *Bates*, 544 U.S. at 447. Put differently, a State cannot supply its own labeling rules,

[7] Plaintiff relies on the Ninth Circuit's decision in *Chemical Specialties Manufacturers Association, Inc. v. Allenby*, 958 F.2d 941 (9th Cir. 1992), but "*Allenby* … never addressed the issue of whether common law damages could be imposed for the absence of these non-label warnings." *Taylor AG Indus. v. Pure-Gro*, 54 F. 3d 555, 561 n.2 (9th Cir. 1995). When the Ninth Circuit did reach that question, it agreed "with the Eleventh Circuit" that a "claim for inadequate point-of-sale warnings is preempted because [it] is premised ultimately upon the inadequacy of the product label." *Id.* at 561.

just "remedies that enforce federal misbranding requirements." *Id.* at 451. And it is not enough for state and federal labeling requirements to be "nominally equivalent"—they must be "*genuinely* equivalent." *Id.* at 454 (emphasis in original). "State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (citing *Bates*, 544 U.S. at 454)).

Monsanto did not violate federal law by failing to warn that glyphosate causes cancer. It compiled with federal law. EPA, following formal, congressionally-mandated procedures, has made a scientific determination that such a warning would be false, and has adhered to that determination across decades. The agency has confirmed that adding a warning that glyphosate causes cancer would cause a pesticide to be misbranded in violation of FIFRA, and that it would not approve the addition of such a warning. As a consequence of EPA's exercise of its delegated authority, a state requirement to warn that glyphosate causes cancer is "in addition to or different from" federal requirements.

1. Under FIFRA, A Pesticide Registrant Cannot Add A Cancer Warning That Contradicts EPA's Scientific Determination Made As Part Of The Registration Process.

FIFRA includes detailed requirements for the labeling of a pesticide—and charges EPA with important responsibilities in implementing those requirements. In particular, EPA plays a critical role in assessing the safety of a pesticide and

determining what safety warnings are appropriate. As the U.S. Government has explained, EPA in carrying out its statutory responsibilities "has never required 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." Supp. App. 032 (Br. of United States as Amicus Curiae in Support of Monsanto, *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir.) ("*Hardeman* U.S. Br.")).

a. No pesticide may be sold in the United States unless EPA has "registered" it—that is, approved it for sale after an extensive scientific review and a determination that the pesticide will not pose an unreasonable risk to human health. *See supra* pp. 6-9; 7 U.S.C. §§136(bb), 136a(a), (c)(1)(F), (c)(2)(A); 40 C.F.R. §§152.20, 158.200. As part of its registration decision, EPA exercises comprehensive control over the labeling of federally registered pesticides. Applicants must submit a "complete copy" of the proposed "labeling of the pesticide." 7 U.S.C. §136a(c)(1)(C). The proposed labeling must comply with extensive regulations governing the contents of pesticide labeling. *See* 40 C.F.R. §156.10. Chief among these requirements, proposed labeling must include detailed "[h]azard and precautionary statements" about the pesticide's impact on human health. *Id.* §§156.10(a)(1)(vii), 156.60.

EPA may not register a pesticide unless it determines that its labeling "compl[ies] with" FIFRA's "requirements." 7 U.S.C. §136a(c)(5)(B). Thus, "EPA will approve an application" for registration "only if," *inter alia*, "[t]he Agency has determined that the product is not misbranded as that term is defined in FIFRA." 40 C.F.R. §152.112(f). This misbranding prohibition includes a requirement that the label contains all necessary health warnings, and that nothing on it is "false or misleading in any particular." 7 U.S.C. §136(q)(1)(A), (G). Once labeling is approved by EPA, all but "minor" changes must likewise be approved by EPA. 40 C.F.R. §§152.44, 152.46; *see also* 7 U.S.C. §136a(c)(9)(C). And every fifteen years, EPA must review a pesticide's registration, including its effects on human health. 7 U.S.C. §136a(g).

"A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used." *Reckitt Benckiser, Inc. v. EPA* ("*Reckitt Benckiser I*"), 613 F.3d 1131, 1133 (D.C. Cir. 2010). FIFRA thus requires compliance with EPA's labeling decisions. It is illegal to sell a pesticide with labeling that makes "any claims" that "substantially differ" from the EPA-approved labeling. *See* 7 U.S.C. §136j(a)(1)(B), (2)(G). FIFRA also makes it illegal to sell a pesticide whose labeling contains "any statement" that is "false or misleading in any particular," which makes the product "misbranded." *Id.* §136j(a)(1)(E), 136(q)(1)(A). Such conduct exposes the violator

to a wide range of enforcement actions, including an order to stop selling the product, civil penalties, and imprisonment. *Id.* §§136k, 136*l*.

b. In Plaintiff's view, EPA's regulatory role under FIFRA should be ignored, and its detailed study of a pesticide's safety and its determination of what warnings should be added are all irrelevant. He suggests that under FIFRA, as long as the state's liability standard is broadly consistent with FIFRA's standards at the highest level of generality, state and federal law are parallel. *See* Pl.'s Br. 20 (arguing that Georgia and federal law are parallel because they "both … require that (1) if known or reasonably knowable information exists showing that the use of Roundup poses a danger, (2) [Monsanto] has a duty to warn of that danger").

That position defies the statutory scheme and the Supreme Court's instructions in *Bates*. The Court expressly cautioned that "nominally equivalent labeling requirements" are in addition to or different from federal requirements if they are not "*genuinely* equivalent." 544 U.S. at 454. Plaintiff's approach—that Georgia and federal law are equivalent because they both require warnings of known dangers—is precisely the sort of "nominal equivalence" that *Bates* rejects. Were that the law, a State could at the highest level of generality purport to adopt FIFRA's standards as state law, but then implement that standard in a manner directly contrary to what federal law requires, undermining the "Uniformity" that §136v(b) mandates.

Indeed, *Bates* confirms that EPA may "give content to FIFRA's misbranding standards." 544 U.S. at 453; *see also id.* at 455 (Breyer, J., concurring) ("[e]mphasizing the importance of the agency's role in overseeing FIFRA's future implementation"). *Bates* explained that where EPA determines that a pesticide should be accompanied by one type of warning (such as "CAUTION"), but a jury concludes under state law that the label should include a more aggressive one (such as "DANGER"), then the state-law rule on which the verdict rests "would be pre-empted" by §136v(b). *Id.* at 453. That is what EPA has done here—except that instead of concluding that glyphosate should receive a "more subdued" warning, *id.*, the agency has concluded that there should be no warning at all.

A state-law requirement to provide a warning that EPA has rejected does not in any meaningful sense "enforce federal misbranding requirements"—it creates additional or different requirements. *Bates*, 544 U.S. at 451. Thus, where even EPA could not bring a misbranding action, a state-law claim cannot be "parallel" to federal misbranding requirements. That is the situation here. When, as here, EPA has exercised its scientific judgment to decide that a warning is not required, the failure to include that warning *cannot* be misbranding: "Congress clearly did not intend to give EPA the authority … to bring a misbranding action" where EPA previously registered a product and determined its safety for "no longer meet[ing] the [registration] criteria" without first following FIFRA's cancellation procedures.

Reckitt Benckiser, Inc. v. Jackson ("*Reckitt Benckiser II*"), 762 F. Supp. 2d 34, 49 (D.D.C. 2011).

c. EPA's record on glyphosate's lack of carcinogenic potential is comprehensive, consistent, and decisive. *See supra* pp. 9-14. In 1993, for example, EPA completed glyphosate's formal re-registration review, following a process mandated by Congress. EPA "determine[d] that glyphosate can be used without resulting in unreasonable adverse effects to man and the environment," and "therefore finds that all products containing glyphosate as the active ingredients are eligible for reregistration." Supp. App. 127 (1993 Reregistration Eligibility Decision). In taking this regulatory action, EPA relied on its 1991 decision to "classif[y] glyphosate in Group E (evidence of non-carcinogenicity for humans), based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse." *Id.* at 084.

Since then, EPA has continually approved the registration and labeling of individual pesticide formulations that include glyphosate. For example, "forty-four versions of the label for the original formulation of Roundup have been accepted by EPA since 1991." Supp. App. 045 (*Hardeman* U.S. Br.).

EPA has continued to review the science on whether glyphosate has carcinogenic potential. Just last year, as part of the registration review process mandated by FIFRA, EPA issued an Interim Registration Review Decision which,

among other things, "finalize[d]" the agency's Human Health Risk Assessment for Registration Review. Supp. App. 395 (Interim Registration Review Decision). EPA "thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." *Id.* Accordingly, while the agency imposed certain interim ecological risk mitigation measures, it found no such measures necessary to protect human health. And following a review resulting from the change in presidential administration, EPA recently informed the Ninth Circuit that it adheres to its determination that glyphosate is not likely to cause cancer. *Supra* pp. 13-14.

Concurrent with its recent registration review, EPA acted in August 2019 to address requests by certain glyphosate registrants to add a cancer warning pursuant to California's Proposition 65. *See* Supp. App. 029 (*Hardeman* U.S. Br.). EPA rejected those requests, and informed registrants that, "[g]iven EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" EPA considers a warning that glyphosate is carcinogenic "to constitute a false and misleading statement" that violates FIFRA's prohibition against "misbranded" substances. Supp. App. 011 (Letter to Registrants (citing 7 U.S.C. §136(q)(1)(A))). The agency therefore instructed that it would not approve the addition of such a cancer warning, and that any such warning must "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." *Id.*[8]

In light of EPA's determination that glyphosate does not cause cancer, there is no federal requirement to warn that glyphosate does cause cancer. To the contrary, FIFRA requires Monsanto *not* to add a cancer warning to Roundup®'s labeling, which EPA has determined would be "false [and] misleading" and make the product "misbranded." 7 U.S.C. §§136(q)(1)(A). The agency has made a formal scientific determination that glyphosate is not a human carcinogen and has approved Roundup® labeling, including precautionary statements, without any cancer warning. Moreover, any warning that contradicts that determination would be false in the eyes of the EPA, and EPA cannot approve any change to the labeling that it concludes contains a false statement. *See, e.g.*, 40 C.F.R. §152.112(f) ("EPA will approve an application" for registration "only if" "[t]he Agency has determined that the product is not misbranded as that term is defined in FIFRA").

[8] The Court should not consider arguments that EPA's glyphosate determinations do not apply to Roundup® as formulated. *See* Farmworker Associations Br. 26-27; Public Justice Br. 10-11. Plaintiff's complaint alleges that the danger of Roundup® concerns "specifically, the active ingredient glyphosate," App. 31-32 (Compl. ¶ 83), and his brief makes no argument that formulated Roundup® raises any separate issues. "[A]rguments raised only by *amici* may not be considered." *Richardson v. Ala. State Bd. of Educ.*, 935 F.2d 1240, 1247 (11th Cir. 1991). In any event, *amici* are wrong. As EPA explained, the agency fully "evaluated the hazard potential (*i.e.*, toxicity) of glyphosate *and any inert ingredients* with a battery of toxicity data from a multitude of studies throughout the risk assessment process." EPA, Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision at 6 (Jan. 16, 2020), https://bit.ly/2AwRLrm. Accordingly, the agency concluded that "all registered uses" of glyphosate are safe for human use. Supp. App. 052 (Interim Registration Review Decision).

2. The *Hardeman* Court Erroneously Denied Effect To EPA's Formal Regulatory Actions On Glyphosate.

In its recent decision in *Hardeman*, the Ninth Circuit recognized that "EPA has repeatedly approved the use of glyphosate as a pesticide, each time concluding that it is not likely to be carcinogenic to humans." *Hardeman*, 2021 WL 1940550, at *4. But it nonetheless concluded that EPA's actions lack "the force of law necessary to have preemptive effect." *Id.* at *8. That decision misunderstands the federal requirements at issue and misreads both FIFRA and *Bates*. Under *Bates*, under the Supreme Court's more recent preemption decisions, and under bedrock principles of administrative law, EPA's formal, repeated, and definitive determination that the science does not support a cancer warning for glyphosate must be given effect.

a. The Ninth Circuit's approach in *Hardeman* was flawed from the outset in its search for "EPA action carrying the force of law," an inquiry it based on implied rather than express preemption case law. *Id.* at *8 (citing *Wyeth v. Levine*, 555 U.S. 555, 576, 580 (2009)) (emphasis omitted). The relevant focus for express preemption purposes is the statutory and regulatory provisions that prohibit a registrant from adding a safety warning that EPA has not approved, and indeed has determined would be false. Those provisions impose "requirement[s]," *i.e.*, "rule[s] of law that must be obeyed." *Id.* (quoting *Bates*, 544 U.S. at 445). And for specific pesticides, those FIFRA requirements are necessarily defined by EPA's pesticide-

specific determinations. Nothing in *Bates* suggests that these agency actions must meet some different "force of law" test.

To the contrary, under the Supreme Court's approach in *Bates*, EPA's pesticide-specific scientific determinations control the express preemption analysis. As noted above, the Supreme Court explained that a state may not require a "DANGER" warning when EPA requires the "more subdued 'CAUTION.'" *Bates*, 544 U.S. at 453. The Ninth Circuit dismissed this example because it involves a "FIFRA regulation" which "'assigns these warnings to particular classes of pesticides based on their toxicity.'" *Hardeman*, 2021 WL 1940550, at *8 n.7 (quoting *Bates* 544 U.S. at 453). That is no distinction at all, because EPA regulations only define toxicity categories and assign each one a warning, *see* 40 C.F.R. §§156.62, 156.64—they do not assign any toxicity category (and thus any warning) to any *particular* pesticide. For that, EPA makes a pesticide-by-pesticide scientific determination, and it does so as part of the formal, statutory registration process—the same process EPA uses to decide whether a pesticide is carcinogenic. *See, e.g.*, Supp. App. 080 (1993 Reregistration Eligibility Decision) (summarizing "the toxicity results and categories for technical grade glyphosate"). It is also the same process EPA uses to decide whether to classify a pesticide for restricted use, which by regulation the agency will consider if it determines the product is

carcinogenic, *see* 40 C.F.R. §152.170(b)(vi), and which results in specific labeling requirements prescribed by regulation, *see* 40 C.F.R. §156.10(j)(2).

Under *Hardeman*'s logic, a state *can* mandate a "DANGER" warning for a pesticide despite EPA's determination that "the more subdued 'CAUTION'" should be used. *Bates*, 544 U.S. at 453. The state can do this by replicating FIFRA and EPA regulations to the letter, but then disagreeing with a specific pesticide's toxicity level as determined by EPA in its registration review, and making its own toxicity finding that triggers a "DANGER" warning— thereby mandating the warning EPA had rejected. That cannot be what *Bates* means or what Congress intended. And it is just as untenable for a state to follow FIFRA's misbranding standard at a high level of generality, but then demand a cancer warning that EPA, as part of its pesticide-specific registration review, has decided is both unnecessary and false.

The importance to the preemption analysis of EPA's glyphosate-specific safety review is further underscored by the Supreme Court's interpretation of the Medical Device Amendments' "similarly worded pre-emption provision." *Bates*, 544 U.S. at 447. Much like FIFRA, the MDA preempts state requirements for medical devices that are "different from, or in addition to, any requirement applicable under this chapter to the device." 21 U.S.C. §360k(a). Also like FIFRA, the Supreme Court interprets the MDA to preempt state law unless the state seeks to impose "parallel requirements." *See Bates*, 544 U.S. at 447 (explaining that the

Court's interpretation of FIFRA "finds strong support" in the Court's interpretation of the MDA).

The Supreme Court's MDA preemption cases do not speak of "agency action with the force of law," but they make clear that the Food and Drug Administration's ("FDA's") safety review and label approval is decisive. FDA's "premarket approval" of a device "imposes 'requirements' under the MDA." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). That is so, *Riegel* holds, because "the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness." *Id.* Thus, "FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.*; *see Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340 (10th Cir. 2015) (Gorsuch, J.) (explaining that "device-specific federal requirements apply" because "the device endured the premarket approval process," and concluding that state-law claims were preempted because "once the FDA approves a device's label as part of the premarket approval process (as it has here), the manufacturer usually may not alter the label's warnings without prior agency approval").[9]

[9] *See also, e.g.*, *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (state-law claim preempted if it "would question the sufficiency of the FDA-approved labeling, warnings, and instructions for the HTA device or require Boston Scientific

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. In *Lohr*, FDA had not conducted premarket approval of the device, but approved it on the basis of "substantial equivalence to a grandfathered device." *Lohr*, 518 U.S. at 493. The key difference, the Court explained in *Riegel*, was that unlike the premarket approval process, "devices that enter the market" based on equivalence have "never been formally reviewed under the MDA for safety or efficacy." *Riegel*, 552 U.S. at 323.

Bates is like *Lohr*, and this case is like *Riegel*. In *Bates*, EPA never reviewed the efficacy claims made on the pesticide's label, *see infra* pp. 39-40, just like in *Lohr*, where FDA never reviewed the grandfathered device's safety or efficacy. Here, EPA extensively examined glyphosate's effects on human health and determined that no cancer warning is appropriate, just like in *Riegel*, where FDA made determinations of safety and efficacy. And just like FDA's "device-specific" regulatory determinations in *Riegel* "impose[d] 'requirements' under the MDA,"

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to have included different warnings, labels, or instructions with the device"); *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (preemption of "additional warnings" beyond the "FDA-approved warnings").

Riegel, 552 U.S. at 322-23, EPA's pesticide-specific regulatory determinations concerning glyphosate impose requirements under FIFRA.[10]

b. Setting aside the poor fit between the Ninth Circuit's "force of law" inquiry and FIFRA's express preemption clause, *Hardeman*'s approach fails on its own terms: EPA's classification of glyphosate as non-carcinogenic was made as part of agency actions that do have the force of law. As the United States has explained, "[t]he EPA approved label is a very formal affair," and "that label (and the associated registration process) establishes 'requirements' sufficient to support a preemption analysis." Supp. App. 039-40 (*Hardeman* U.S. Br.).

The Supreme Court has long recognized that agency action other than rulemaking and formal adjudication can carry the force of law: "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." *United States v.*

[10] The Ninth Circuit's sole basis for distinguishing *Riegel* was that the MDA lacks "a provision like FIFRA's §136a(f)(2)," which "clarifies that the agency's approval of a label is not determinative of compliance with the statute." *Hardeman*, 2021 WL 1940550, at *7 n.6. As explained below, *infra* pp. 37-39, §136a(f)(2) is irrelevant—it concerns enforcement proceedings, not preemption. Even if it were relevant, preemption here does not depend on mere registration. A provision like §136a(f)(2) is not necessary to "clarif[y]" that "the agency's approval of a label is not determinative," *Hardeman*, 2021 WL 1940550, at *7 n.6, because the same is true under the MDA without such a provision—*Lohr* shows that FDA approval alone is not determinative of anything. It was FDA's *safety determination* in its premarket approval process that created device-specific federal requirements in *Riegel*, just like it is EPA's *safety determination* in its registration process that creates pesticide-specific federal requirements here.

Mead, 533 U.S. 218, 230-31 (2001) (emphasis added). Applying this principle to the preemption context (albeit implied preemption), the Court has cited several FDA processes that do not employ rulemaking or formal adjudication that can carry the force of law and have preemptive effect. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). For example, the Court in *Merck* explained that a federal agency may "communicate its disapproval" of a proposed labeling change through a variety of methods, including a letter to an applicant stating its position on a drug. 139 S. Ct. at 1679 (citing 21 C.F.R. §§314.110(a), 314.125(b)(6)); *see also infra* pp. 51-52.

EPA's formal re-registration and registration review procedures bear all the hallmarks of formal agency action. *See* Supp. App. 394-405 (Interim Registration Review Decision); Supp. App. 079-126 (1993 Reregistration Eligibility Decision). Re-registration encompasses five distinct phases, culminating in "regulatory action." 7 U.S.C. §136a-1. Glyphosate was re-registered pursuant to this statutory process in 1993, in proceedings that included notice and comment. Supp. App. 127-28 (1993 Reregistration Eligibility Decision). Similarly, registration review entails the submission and review of voluminous data regarding the pesticide's safety, requires notice and comment, and yields a definitive determination by EPA about the warnings to appear on the pesticide's label. *See* 7 U.S.C. §136a(g); 40 C.F.R. §155.50(b)-(c). Applying well-settled principles of administrative law, the agency's

actions on glyphosate were done through "procedure[s] tending to foster … fairness and deliberation," and regulatory decisions made as part of such a formal, congressionally-prescribed agency process carry the force of law. *Mead*, 533 U.S. at 230.

Ordinarily, it would not be controversial to recognize that formal agency actions that endure a notice-and-comment process carry the force of law. The Ninth Circuit never doubted this proposition, or the formality of the procedures EPA used with respect to glyphosate. Instead, *Hardeman* avoided the normal operation of administrative law principles by focusing on a provision of FIFRA stating that "registration of an article" may not "be construed as a defense for the commission of any offense under this subchapter," but is instead "prima facie evidence" that the product complies with FIFRA. 7 U.S.C. §136a(f)(2).

That statutory text—which appears under the statutory heading "Miscellaneous," *see id.*—cannot bear the weight of the *Hardeman* court's conclusion. As the Fifth Circuit has concluded, §136a(f)(2) "has no bearing on" preemption: "A claim grounded in state common law is not an offense under FIFRA. Thus, §136a(f)(2) does not apply." *MacDonald v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994).[11]

[11] *MacDonald* pre-dates *Bates*, but nothing in *Bates* undermines its interpretation of §136a(f)(2); *Bates* only referenced that provision once, with a passing "see also" citation, while discussing the statutory background. *See* 544 U.S. at 438.

Even if the provision did imply that "registration of an article" is insufficient for preemption, it would have no relevance here. "Section [136a(f)(2)] stands for the unremarkable proposition that a registration is not a defense against an allegation that a product violates the terms of that registration, just as a valid driver's license is not a defense against a speeding ticket." *Reckitt Benckiser II*, 762 F. Supp. 2d at 45. So if, for example, a registrant omits an EPA-required warning from its label, registration would not be a defense to an EPA misbranding enforcement action, and a state tort claim enforcing the federal misbranding provision would not impose any requirements that are different from or in addition to federal requirements. *Cf. In re Medtronic*, 623 F.3d at 1205 (claim that device-maker "modified or failed to include FDA-approved warnings" would not be preempted by MDA). Similarly, if a registrant added an unapproved cancer warning to the label of a glyphosate product, the pesticide's registration would be no defense to a misbranding charge.

But *Hardeman* reads §136a(f)(2) as doing much more, to the point that it would effectively nullify FIFRA's preemption provision. As long as state tort law and the federal misbranding provision are consistent at a high level of generality, states would be free to impose labeling requirements different from or in addition to what EPA has decided the label should say. That is not "Uniformity" at all, and Congress could not have meant a "Miscellaneous" provision to override FIFRA's "Uniformity" provision. *See Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457,

468 (2001) (Congress does not "hide elephants in mouseholes"). Instead, both provisions can and should be read in harmony, in a manner giving meaning to both: §136a(f)(2) ensures that registration is not a defense when a registrant deviates from the approved label or violates one of FIFRA's many other requirements, while §136v(b) ensures national uniformity in labeling when EPA has decided what warnings should and should not be given.

Put simply, and contrary to *Hardeman*'s reasoning, FIFRA's proviso that registration is not a defense to a misbranding enforcement action is irrelevant to a case, like this one, where the mere fact of registration is not the basis of preemption. EPA's formal scientific determination that glyphosate does not cause cancer and determination that, accordingly, no cancer warning is warranted, compels preemption because of the formal, congressionally-mandated procedures EPA used to make it—not because of the bare fact that EPA registered the pesticide.

Bates illustrates the difference between mere approval of a pesticide—which was the proposed basis for preemption in that case—and an agency determination about a particular safety issue. In *Bates*, the plaintiff alleged that state law required an efficacy warning, *i.e.*, that Strongarm should not be used to protect peanut crops in certain soils. 544 U.S. at 435. But EPA approval of a pesticide and its label "*does not reflect any determination on the part of EPA* that the pesticide will be efficacious or will not damage crops or cause other property damage," because Congress

authorized EPA to waive efficacy review. *Id.* (emphasis added) (quoting EPA, Pesticide Registration Notice 96-4 at 3 (June 3, 1996)). The Supreme Court relied on EPA's waiver of efficacy review as supporting its interpretation of §136v(b). *See id.* at 150. And the absence of any EPA efficacy review or determination examining this potential for crop damage animated *Bates*'s observation that tort suits can "aid in the exposure of new dangers associated with pesticides." *Id.* at 451 (quoting *Ferebee v. Chevron Chemical Co.*, 736 F. 2d 1529, 1541-42 (D.C. Cir. 1984)).

This case presents a very different situation. EPA, as part of the formal registration process and approval of Roundup®'s labeling, *has* consistently made determinations about the adequacy of Roundup®'s safety warnings, and about the alleged cancer risk in particular. Tort suits alleging that glyphosate causes cancer will not expose new dangers—EPA has thoroughly evaluated the science, including the precise scientific evidence being put forward by plaintiffs in Roundup® litigation, *see infra* p. 47 & n.14, and repeatedly classified glyphosate as non-carcinogenic. Here, a tort suit would hold a manufacturer liable for not including a warning that the agency has determined would be false, that the manufacturer cannot provide without the agency's approval, and that the agency *could not* approve in light of its scientific determination. And the agency has decided all of this in the course of "a relatively formal administrative procedure tending to foster … fairness and deliberation"—the type of procedure that under binding Supreme Court

precedent yields "administrative action with the effect of law." *Mead*, 533 U.S. at 230-31.

c. Plaintiff and his *amici* largely disregard EPA's classification of glyphosate as non-carcinogenic as part of its formal registration procedures, focusing instead on EPA's August 2019 letter. *See, e.g.*, Public Citizen Br. 14-16; Public Justice Br. 15-22. In addition to being misplaced, those criticisms are beside the point. EPA's decisions classifying glyphosate as non-carcinogenic as part of its re-registration and registration review, EPA's countless approvals of glyphosate-based products, and its determinations regarding carcinogenicity in its notice-and-comment proceedings to establish tolerances, are independently sufficient to compel preemption. While the August 2019 EPA letter adds force to that conclusion, even setting it aside would not change the outcome.

EPA's letter only confirms what has long been clear: the agency will not approve a cancer warning for glyphosate, making it unlawful for companies like Monsanto to add the warning Plaintiff seeks. The agency's letter responded to requests from certain registrants to add a cancer warning to their glyphosate-based products in response to a purported requirement of California law. *See* Supp. App. 029-30 (*Hardeman* U.S. Br.). In response, EPA informed registrants that it decided to deny those requests, explaining that such a warning would make their products misbranded. Supp. App. 011 (Letter to Registrants). That "authoritative

interpretation of [EPA's] FIFRA misbranding authority … has practical and significant legal effects." *Reckitt Benckiser I*, 613 F.3d at 1138. It commits EPA to rejecting requests to add such a cancer warning, and directs registrants to remove any such warnings from their labeling or face legal consequences. *See* 7 U.S.C. §136*l*. And in communicating this decision to registrants, EPA relied on the cancer determination it had made as part of the formal registration process described above. Supp. App. 011-12 (Letter to Registrants).

The Ninth Circuit declined to give the August 2019 letter effect on the view that it did nothing more than "express[] an informal policy opinion." *Hardeman*, 2021 WL 1940550, at *8 (quoting *Fellner v. Tri-Union Seafoods, LLC*, 39 F.3d 237, 255 (3d Cir. 2008)). The court analogized EPA's letter to a letter FDA had sent to the State of California, after California had sued to require a warning about mercury in tuna fish, in which FDA "express[ed] the opinion that the FDA's prior regulatory actions preempt the State's lawsuit." *Fellner*, 39 F.3d at 241. Yet the reason the Third Circuit denied FDA's letter preemptive effect was that it "was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone." *Id.* at 345. Here, by contrast, EPA's letter expressly informed registrants of their legal obligations as a result of EPA's cancer determination. It was also issued in response to requests to add a warning, under a legal regime that—unlike the one in *Fellner*—requires agency approval for such a

warning. A letter that states how an agency has decided to exercise its authority, and what regulated entities must therefore do, is not an "informal policy opinion."

The cases Plaintiff cites only confirm how formal and authoritative EPA's actions concerning glyphosate—both its registration decisions and the August 2019 letter—have been. In *Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.*, the defendant invoked the "Background" section of an EPA "Notice" of "Revised Policy"—a "policy revision [that] was not applicable to" the pesticide at issue. 617 F. 3d 207, 223 (3d Cir. 2010). The Third Circuit explained that it would be "reluctant to base a preemption holding on a background observation of the kind relied upon by Novartis." *Id.* at 224. Here, Monsanto does not rely on a background observation in a policy statement; it relies on EPA's authoritative determinations about the safety of glyphosate and its labeling, made as part of the formal regulatory process prescribed by Congress. Similarly, in *Reid v. Johnson & Johnson*, the enforcement letter invoked by the defendant was insufficiently formal because it was "equivocal," "tentative," and "non-committal." 780 F.3d 952, 965 (9th Cir. 2015). There is nothing equivocal, tentative, or non-committal about EPA's consistent determination that glyphosate is not likely to cause cancer, or its August 2019 letter

explaining how it is exercising its authority under FIFRA and what regulated entities must do as a result.[12]

***

As a result of EPA's formal and authoritative actions concerning glyphosate, there is no federal requirement to change Roundup®'s labeling to warn that glyphosate causes cancer—there is a federal requirement *not* to make such a change. Yet state law, according to Plaintiff, required Monsanto to make that change and add a cancer warning that EPA has never required and has determined would be false. That alleged state-law requirement is "in addition to or different from" federal labeling requirements under FIFRA, so it is expressly preempted. 7 U.S.C. §136v(b).

II. Plaintiff's State-Law Failure-to-Warn Claim Is Also Barred By Impossibility Preemption.

In addition to falling within FIFRA's express preemption provision, Plaintiff's failure-to-warn claim is barred by impossibility preemption. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-72 (2000) (noting that an "express pre-

[12] Plaintiff is also not aided by citing various out-of-circuit, mostly unpublished district court opinions in other Roundup® cases. *See* Pl.'s Br. 11-16. These decisions mostly pre-date EPA's 2019 letter and 2020 Interim Registration Review Decision. More importantly, they are unpersuasive for the reasons discussed above. The only appellate court to address the preemption issue, apart from *Hardeman*, is a decision of the California Court of Appeal, which notably declined to publish its preemption analysis because it was based on the specific record in that case, which in the court's view meant its decision "provide[s] little guidance to parties in future cases." *Johnson v. Monsanto Co.*, 52 Cal. App. 5th 434, n.* (2020).

emption provision" does not "bar the ordinary working of conflict pre-emption principles").[13]

State law is impliedly preempted "where it is 'impossible for a private party to comply with both state and federal requirements.'" *Bartlett*, 570 U.S. at 480 (citation omitted). In the years since *Bates*, the Supreme Court has elaborated on impossibility preemption, particularly in the drug context. *See Hardeman*, 2021 WL 1940550, at *9 ("regulatory preemption in other contexts has developed considerably" since *Bates*). While drug manufacturers can, under certain limited circumstances, unilaterally add a new safety warning to the drug's labeling, "FDA retains authority to reject [such] labeling changes." *Wyeth*, 555 US at 571. Where FDA would exercise that authority, it is impossible for a drug manufacturer to comply with a state-law warning requirement. Accordingly, if there is "'clear evidence' that the FDA would not have approved a change to the drug's label," such a determination "pre-empts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the drug." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019) (quoting *Wyeth*, 555 U.S. at 571).

[13] The district court concluded that Plaintiff's non-warning claims were not impliedly preempted, but it did not consider whether impossibility preemption under the *Wyeth*/*Merck* framework bars Plaintiff's failure-to-warn claim. App. 98-103. This Court may affirm the district court's dismissal on that alternative ground.

As the Supreme Court elaborated in *Merck*, this form of preemption applies where (1) the agency was "fully informed" of "the justifications for the warning" the plaintiff demands, (2) the agency has "informed the … manufacturer that [it] would not approve changing the … label to include that warning," and (3) the agency's action "carr[ies] the force of law." *Id.* at 1678-79. While *Wyeth* used the phrase "clear evidence," *Merck* makes clear that the question is "a matter of law for the judge to decide." *Id.* at 1679.

Under FIFRA, a registrant likewise cannot change its labeling to add a warning that EPA would reject. *See* 40 C.F.R. §152.112(f); *supra* pp. 24-25. At a minimum, therefore, if there is clear evidence that EPA would not approve a warning that glyphosate causes cancer, a state-law claim for failure to provide such a warning is barred by impossibility preemption. *Accord Hardeman*, 2021 WL 1940550, at *9 (acknowledging that impossibility preemption would apply if the clear evidence standard is met). There is no question that EPA would not approve a warning that glyphosate causes cancer, so it was impossible for Monsanto to provide such a warning without violating federal law.

A. EPA Has Been Fully Informed Of The Supposed Justifications For A Warning That Glyphosate Causes Cancer.

EPA is "fully informed" of "the justifications for the warning required by state law"—*i.e.*, the evidence that glyphosate is allegedly carcinogenic. 139 S. Ct. at 1678. As described above, the agency has repeatedly undertaken in-depth scientific

reviews of the evidence on glyphosate's safety, and has concluded that it is not carcinogenic. *See supra* pp. 9-14. Each time, EPA's determination was based on an extensive review of the scientific evidence. The agency has "considered a more extensive dataset than IARC," the body whose cancer assessment is central to Plaintiff's claim. Supp. App. 011 (Letter to Registrants); *see* App. 21-25 (Compl. ¶¶ 35-51 (describing IARC's report)). Indeed, as part of its notice-and-comment procedures, EPA considered the precise arguments and evidence that Plaintiffs have relied on before juries in the Roundup litigation.[14] The nearly 283,300 comments EPA received during a 120-day comment period in 2019 "did not result in changes to the agency's risk assessments." Supp. App. 390 (Interim Registration Review Decision).

Even though glyphosate is one of the most studied chemicals in the world, *Amicus* Public Justice asserts that Monsanto should have done more testing, and on that basis argues that EPA was not "fully informed." Public Justice Br. 24-25. But one can always theorize more testing, and if the mere prospect of some additional testing were sufficient, no agency could ever be "fully informed." And of course the

[14] *See, e.g.*, EPA, Glyphosate Registration Review Docket, Docket ID: EPA-HQ-OPP-2009-0361, Additional Comments of Christopher J. Portier, PhD. to the FIFRA Scientific Advisory Panel, Attach. to Comment Submitted by Nat'l Res. Defense Council on EPA Notice: Registration Review: Draft Human Health and/or Ecological Risk Assessments for Several Pesticides (posted July 3, 2018), https://www.regulations.gov/docket?D=EPA-HQ-OPP-2009-0361; *see also Hardeman*, 2021 WL 1940550, at *15 (describing Dr. Portier's testimony as an expert for the plaintiff during the *Hardeman* trial).

agency has the ability to seek more testing if it believes it is necessary. In the 1980s EPA did exactly that, calling for additional studies that led to its 1991 classification of glyphosate as non-carcinogenic. *See* Supp. App. 179-80 (EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017)). Since then, the agency has reaffirmed its cancer determination on the basis of the robust evidence before it—including everything that Plaintiff and his *amici* believe support their opposite conclusion. *See* Supp. App. 405 (Interim Registration Review Decision) ("No additional data are required for this registration review at this time."). "[T]he [federal agency], and only the [federal agency], can determine what information is 'material' to its own decision to approve or reject a labelling change." *In re Avandia Mktg., Sales & Prod. Liab. Litig.*, 945 F.3d 749, 759 (3d Cir. 2019) (rejecting preemption where FDA letter stated that "the information presented is inadequate" to make a determination on the proposed warning).

B. EPA Has Made It Clear It Would Not Approve A Warning That Glyphosate Causes Cancer.

EPA has also "informed" registrants of glyphosate-based products, including Monsanto, that it "would not approve changing … the label to include [a cancer] warning." *Wyeth*, 139 S. Ct. at 1678-79.

It has long been clear that EPA would not approve such a warning. For example, in 1993, EPA formally concluded that glyphosate met the requirements for

re-registration under FIFRA, based in part on its 1991 decision "classif[ying] glyphosate in Group E (evidence of non-carcinogenicity for humans)." Supp. App. 084 (1993 Reregistration Eligibility Decision). Having formally classified glyphosate as non-carcinogenic, EPA *could not* have approved a warning that it viewed as including a false statement, *i.e.*, that glyphosate causes cancer. A false warning makes a pesticide misbranded, and EPA has a statutory duty not to approve labeling that would violate FIFRA's misbranding prohibition. *See supra* p. 24.

EPA's conclusion that glyphosate is not likely carcinogenic in humans has continued without interruption. *See supra* pp. 9-14. The agency's recent letter informing all glyphosate registrants that it would not approve the addition of a cancer warning to product labels underscores what has been true for decades: EPA does not believe glyphosate is a carcinogen, EPA views a cancer warning in these circumstances as false and misleading in violation of FIFRA, and EPA "would not approve changing the [product's] label to include" such a warning. *Merck*, 139 S. Ct. at 1678-79.[15]

[15] Contrary to what *Amici* argue, nothing in the agency record suggests that EPA would have approved cancer warnings prior to 2019. *See* Public Citizen Br. 18-19; Public Justice Br. 18. As the United States has explained, two glyphosate registrants were initially permitted to add language pursuant to California's Proposition 65, but those registrants presented the change only "as a statement about California's assessment," without properly framing the warning as a "Human Hazard and Precautionary Statement." Supp. App. 029 (*Hardeman* U.S. Br.). As a result, the change "did not receive" the appropriate "level of review" from the agency, leading to what the United States explains were "implementation mistakes," which were "erroneous because the proposed edits warned of a cancer risk that, according to EPA's assessment, does not exist." *Id.* at 10, 17. Isolated implementation mistakes,

C. EPA's Actions Have The Force Of Law.

As explained above, the clear evidence that EPA would not have approved a cancer warning comes from repeated agency actions carrying the force of law. *See supra* pp. 35-44. EPA has made cancer classifications as part of the formal, congressionally-prescribed re-registration and registration review processes that included extensive notice and comment. *See* Supp. App. 386-421 (Interim Registration Review Decision); Supp. App. 061-144 (1993 Reregistration Eligibility Decision). It has repeatedly approved the registration of individual pesticides containing glyphosate, and approved labels that lack a cancer warning. *See supra* p. 27. It has made determinations about glyphosate's lack of carcinogenic potential in setting pesticide tolerances by notice-and-comment rulemaking. *See*, *e.g.*, Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002); Final Rule: Glyphosate, Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008). And in response to registrants who sought to add a cancer warning to comply with California's Proposition 65 requirements, EPA informed all glyphosate registrants that it will not approve a warning that glyphosate causes cancer because adding such a warning would render the product misbranded. Supp. App. 011-12 (Letter to Registrants).

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in which EPA briefly and erroneously approved a statement about "California's assessment" of glyphosate, does nothing to undermine the clear evidence that EPA would have rejected a precautionary statement warning that glyphosate causes cancer.

The supposed lack of any EPA action with the force of law was the sole reason why the Ninth Circuit in *Hardeman* held impossibility preemption under the clear evidence standard inapplicable. *See Hardeman*, 2021 WL 1940550, at *8. As explained above, that conclusion is based on an erroneous inference from a FIFRA provision stipulating that in an enforcement proceeding, mere registration of a pesticide is not a complete defense to a FIFRA violation. *See id.* That provision—§136a(f)(2)—does nothing to undermine the formality and fairness of the procedures used by EPA to reach its scientific determination classifying glyphosate as non-carcinogenic, and it is irrelevant to the preemptive effect such a determination has. *See supra* pp. 37-39.

Any conclusion that EPA's actions lack the force of law cannot be reconciled with *Merck*, which recognized far more informal communications of an agency's position as having preemptive effect. *See Merck*, 139 S. Ct. at 1679 (citing 21 C.F.R. §§314.110(a), 314.125(b)(6), an FDA process by which the agency merely communicates its official position on an individual drug to an applicant in a "complete response letter"); *see also Cerveny v. Aventis, Inc.*, 783 F. App'x 804, 808 (10th Cir. 2019) (concluding, post-*Merck*, that preemption was established where the agency "rejected [a] citizen petition advocating for the warning").

Indeed, *Merck* noted that in *addition* to the agency "formally rejecting a warning label," preemption can be supported by "other agency action carrying the

force of law," citing as an example 21 U.S.C. §355(o)(4)(A). 139 S. Ct. at 1679. As further explained by Justice Alito in a three-Justice concurrence, that statutory provision "imposed on the FDA a duty to initiate a label change" if it becomes aware of new safety information warranting such a change. *Id.* at 1684 (Alito, J., concurring). This provision is "highly relevant to the pre-emption analysis," because "if the FDA declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified." *Id.* at 1684-85; *accord In re Incretin-Based Therapies Prod. Liab. Litig.*, __ F. Supp. 3d ___, No. 13-md-2452-AJB-MDD, 2021 WL 880316, at *16 (S.D. Cal. Mar. 9, 2021) (holding that, in light of §355(o)(4)(a), "the Court cannot simply ignore the FDA's demonstrated commitment to actively and continuously monitoring the pancreatic safety of incretin mimetics" and the agency's decision not to require a warning); *Ridings v. Maurice*, 444 F. Supp. 3d 973, 998 (W.D. Mo. 2020) ("in light of the known issues and the ongoing give-and-take between Boehringer and the FDA on these issues …, the FDA's continued inaction does represent clear evidence under these facts.").

Just as FDA has a statutory "duty to initiate a label change" if it becomes aware of information necessitating a warning, *Merck*, 139 S. Ct. at 1684 (Alito, J. concurring), EPA has a statutory duty not to approve a pesticide's label 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); *id.* §136a(c)(5)(B); *id.* §136j(a)(1)(E). And here, there is no need to infer as a "logical conclusion" that EPA "determined that a label change was unjustified," *Merck*, 139 S. Ct. at 1684 (Alito, J. concurring)—EPA has said so. Since FDA's decision pursuant to §355(o)(4) not to require a label change is an "other agency action carrying the force of law" with preemptive effect, *Merck*, 139 S. Ct. at 1679 (majority op.), EPA's even more formal actions declining to require a cancer warning for glyphosate must necessarily have preemptive effect.

D. *Bates* Did Not Reject Impossibility Preemption "*Sub Silentio*."

Amicus Public Justice asks this Court not even to apply normal principles of impossibility preemption, on the theory that the Supreme Court in *Bates* somehow rejected it "*sub silentio*." Public Justice Br. 23. Resort to the phrase "*sub silentio*" reflects a recognition that *Bates* did not actually hold this—it said nothing about implied preemption of any kind. And it is demonstrably wrong that the Supreme Court "*had* to consider any arguments that, if successful, would have affirmed the lower court decision finding preemption." *Id.* at 23 (quoting *Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270, 1281-82 (D. Haw. 2015)). The court of appeals decision in *Bates* turned solely on express preemption, *see Dow Agrosciences LLC v. Bates*, 332 F.3d 323, 329 (5th Cir. 2003), and the Supreme Court has no obligation to consider every alternative ground, especially one not passed on by the lower court. The Supreme Court frequently cautions against

assuming it has ruled on "[q]uestions which merely lurk in the record." *See Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 170 (2004).

Nor was the case for impossibility preemption in *Bates* remotely as strong as it is here. In *Bates*, the plaintiff sought an efficacy warning on which EPA had never made any determination (since the agency had exercised its statutory authority to waive efficacy review), so there could not have been clear evidence that EPA would reject such a warning. *See* 544 U.S. at 440. Anything the Supreme Court might have concluded "*sub silentio*" in *Bates* would not rule out impossibility preemption in the very different situation presented here.

In this case, federal law made it impossible for Monsanto to warn that glyphosate causes cancer in light of EPA's clear, consistent, and definitive rejection of the view that glyphosate causes cancer. Nothing in *Bates* suggests that in the pesticide context alone, state law can impose liability for refusing to defy a federal agency and violate federal law.

CONCLUSION

For the foregoing reasons, this Court should affirm the district court's judgment of dismissal.

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Respectfully submitted,

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), it contains 12,990 words.

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CERTIFICATE OF SERVICE

I hereby certify that on June 4, 2021, I caused the foregoing document to be electronically filed with the United States Court of Appeals for the Eleventh Circuit using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to counsel of record.

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ADDENDUM

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7 U.S.C. §136 Definitions

For purposes of this subchapter—

* * *

(p) Label and labeling

(1) Label
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.

(2) 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 current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

* * *

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or

displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

* * *

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

7 U.S.C. §136a Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

* * *

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

* * *

(c) Procedure for registration

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

* * *

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

* * *

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

* * *

7 U.S.C. §136a-1 Reregistration of registered pesticides

(b) Reregistration phases

Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

7 U.S.C. §136j Unlawful acts

(a) In general

(1) Except as provided by subsection (b) of this section, it shall be unlawful for any person in any State to distribute or sell to any person—

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) 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 under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

* * *

7 U.S.C. §136v Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) Additional uses

> (1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.
>
> (2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.
>
> (3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] that permits the residues of the pesticides on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a

State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 136w of this title, that a State is not capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this subchapter or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.

40 C.F.R. §155.58 Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the Federal Register announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide's registration review docket the Agency's proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:

(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency's response to significant comments. The Agency will publish a notice in the Federal Register announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the registration review case have been completed.

(d) If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA.

40 C.F.R. §156.10 Labeling requirements

(a) *General*—

(1) *Contents of the label.* Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

* * *

(a) *General*—

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed”; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

* * *

(i) *Directions for Use—*

(1) *General requirements—*

(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

* * *

(i) *Directions for Use—*

(1) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Worker protection statements meeting the requirements of subpart K of this part.

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part. These instructions must be grouped and appear under the heading, "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in §156.60(b))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) For total release foggers as defined in §156.78(d)(1), the following statements must be included in the "Directions for Use."

* * *

(j) *Statement of use classification.* Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.*

(A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

40 C.F.R. §156.60 General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements*—

(1) Front panel statements. The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) Statements elsewhere on label. Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence*—

(1) Front panel statements. All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

* * *

40 C.F.R. §156.70 Precautionary statements for human hazards

(a) *Requirement.* Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading "Precautionary Statements" and under appropriate subheadings similar to "Humans and Domestic Animals," "Environmental Hazards" (see subpart E of this part) and "Physical or Chemical Hazards." The phrase "and Domestic Animals" may be omitted from the heading if domestic animals will not be exposed to the product.

(b) *Content of statements.* When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) *Typical precautionary statements.* The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to §156.68(b) for requirements for use dilution statements.

* * *