The Florida Justice Reform Institute Supports Exempting Manufacturers, Distributors, Sellers, and Applicators of Pesticides from Certain Product Liability Actions for Pesticides that Meet Federal and State Requirements

Introduction

Pesticide manufacturers, distributors, and sellers are required to comply with requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq., in selling and labeling pesticides. FIFRA requires all pesticides to be registered with the United States Environmental Protection Agency (EPA), which requires the pesticide manufacturer to show that the pesticide does not cause any unreasonable adverse effect on human health or the environment when used properly. During the registration process, the EPA determines the information, including all warnings, the pesticides labeling must contain in order for the pesticide to be safely used, and no information or warnings on pesticide labels may be changed without EPA approval. The requirements of FIFRA and EPA regulations governing pesticides ensure that the safety of pesticides necessary to the farming industry are evaluated under science-based protocols and provide uniformity in pesticide use and labeling across the nation. For pesticides sold and used in Florida, these safety requirements are also reviewed and evaluated by the Florida Department of Agriculture and Consumer Services.

Notwithstanding FIFRA's objectives, recent cases against Monsanto, the manufacturer of the herbicide commonly known as Roundup, have imposed liability on the manufacturer, even though the EPA has repeatedly reviewed scientific data to determine that Roundup's active ingredient, glyphosate, presents no unreasonable risk to human health when used as directed, and the warnings on Roundup's labeling are adequate and complete. These cases have opened the floodgates to litigation against Roundup's manufacturers, distributors, sellers, and applicators and are resulting in the unworkable patchwork of state-law requirements for pesticides that FIFRA was intended to prevent.

Farmers depend on Roundup and other pesticides to manage pests and control plant diseases that can destroy crops and threaten a reliable and affordable food supply. Subjecting pesticide manufacturers, distributors, sellers, and applicators to out-of-control litigation risk for state-law products liability claims even though the pesticides comply with comprehensive federal requirements, reduces farmers' ability to protect crops and maintain important conservation practices, and threatens food availability and affordability across the nation.

To protect Florida's food supply and ensure the uniform, science-based requirements of FIFRA and the EPA are applied to the use of agricultural pesticides in Florida, the Legislature should create a sensible exemption from failure to warn and design defect products liability actions for the distribution, sale, or application of agricultural pesticide products that comply with FIFRA and Florida regulatory requirements.

Overview of Comprehensive FIFRA and EPA Requirements for Registration and Labeling of Pesticides

Pesticides are substances that prevent, destroy, repel, or mitigate pests, such as bacteria, insects, rodents, and weeds, that damage or destroy crops and other beneficial plants. Although pesticides often contain chemicals that can be harmful if not used properly, their use is necessary to farmers and others in the agricultural industry because the prevention and mitigation of crop-destroying pests is critical to producing a reliable and affordable food supply. FIFRA and the EPA regulations promulgated thereunder create a comprehensive, nationwide regime that balances the necessity of pesticide use with the need to ensure—based on robust scientific data—that pesticides can be safely used as directed by proper labeling.

1. The EPA's Exhaustive Pesticide Registration Process

FIFRA requires all pesticides distributed or sold in the United States to be registered with the EPA and authorizes the EPA to restrict the sale or use of pesticides that present "unreasonable adverse effects on the environment," 7 U.S.C. § 136a, including "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," 7 U.S.C. § 136(bb). "This is commonly referred to as the FIFRA safety standard." *Nat. Res. Def. Council v. U.S. Envtl. Prot. Agency*, 38 F.4th 34, 40 (9th Cir. 2022). Thus, before a pesticide product can be lawfully sold or distributed, the EPA performs a robust scientific assessment of the product, resulting in a regulatory decision regarding whether or not to approve the product for registration. *See* 40 C.F.R. § 152.15. Pesticides that do not meet the FIFRA safety standard may not be registered for sale and use in the United States. *See* 7 U.S.C. § 136a(c)(5)(C); *see also* 40 C.F.R. § 152.112(e).

In seeking to have a pesticide registered, the pesticide's manufacturer or other applicant must submit robust scientific data to the EPA which addresses concerns about the pesticide's identity, composition, potential adverse effects, and environmental impact. This data allows the EPA to evaluate whether the pesticide might adversely affect a range of non-target organisms, including humans, plants, animals, and endangered or threatened species.

During the registration process, the EPA conducts, among other things, a human health risk assessment of the pesticide. *See Assessing Human Health Risk from* Pesticides, EPA.gov, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides (last visited Jan. 2, 2025). This assessment estimates the nature and probability of adverse health effects in humans who may be exposed to the pesticide's chemicals contained in soil, water, air, biota (plants and animals), or any other parts of the environment. *Id.* The EPA assesses the types of health problems posed by exposure to the pesticide, the chance that exposure will result in health problems, and other concerns to human health. *See id.* As a part of this process, the EPA reviews all scientific data on the pesticide and develops a comprehensive risk assessment of the pesticide. *See id.* If a pesticide does not meet the FIFRA safety standard, after considering all appropriate risk reduction measures, the EPA will not allow the pesticide to be registered. *See About Pesticide Registration*, EPA.gov, https://www.epa.gov/pesticide-registration/about-pesticide-registration (last visited on Jan. 2, 2025).

As part of its human health risk assessment, the EPA performs a carcinogen risk assessment of the pesticide, in which the EPA reviews the pesticide for "potential carcinogenicity." *Evaluating Pesticides for Carcinogenic Potential*, EPA.gov, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential (last visited Jan. 2, 2025). Based on this assessment, the EPA classifies the pesticide as (i) carcinogenic to humans, (ii) likely to be carcinogenic to humans, (iii) suggestive evidence of carcinogenic potential, (iv) inadequate information to assess carcinogenic potential, or (v) not likely to be carcinogenic to humans. EPA, Guidelines for Carcinogen Risk Assessment, at 2-56–2-58 (Mar. 2005), https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf. If the agency determines that a pesticide is carcinogenic, it will consider limiting permissible applications through a restricted use classification, *see* 40 C.F.R. § 152.170(b)(vi), and imposing "labeling requirements intended to protect human health," *Nat. Res. Def. Council*, 38 F.4th at 45. The EPA makes these expert determinations only after analyzing exhaustive scientific data. *See* 7 U.S.C. §§ 136a(c)(1)(F), (2)(A); 40 C.F.R. § 158.500.

The EPA also conducts an ecological risk assessment to determine what risks to the environment are posed by the pesticide and whether changes to the use or proposed use of the pesticide are necessary to protect the environment. *See About Pesticide Registration*, EPA.gov, https://www.epa.gov/pesticide-registration/about-pesticide-registration (last visited on Jan. 2, 2025). Before allowing a pesticide product to be sold on the market, the EPA ensures that the pesticide will not pose any unreasonable risks to plants, wildlife, and the environment. *See id.*

Following its human health and ecological risk assessments, the EPA develops comprehensive risk findings, which provide information on the economic, social, and environmental costs of the use of a pesticide by evaluating the potential effects on human health and the environment from legal use of a pesticide. *See id.* The human health and environmental risk assessments undergo a process of peer review by scientific experts, generally within EPA. *See id.* Thereafter, the EPA issues a notice in the Federal Register which indicates whether the EPA intends to issue a registration for the pesticide and includes information on the EPA's: (i) risk assessments of the pesticide; (ii) benefit assessments, if any; (iii) determination of whether the proposed uses of the pesticide generally cause unreasonable risks (taking into account the costs and benefits of the use of the pesticide) or fail to meet the Federal Food, Drug, and Cosmetic Act (FFDCA) safety standard; (iv) determination of whether additional mitigation measures on the pesticide product label can address any risks deemed unreasonable; and (v) determination of whether risks or reasonable or can be reduced to no longer unreasonable with additional mitigation measures. *See id.*

The EPA's supervision of a pesticide continues after an application to register the pesticide is approved. Specifically, FIFRA obligates a registrant to inform the EPA if, following registration, the registrant learns of new information concerning a pesticide's risks to human health or the environment. 7 U.S.C. § 136d(a)(2). The EPA is also authorized to revisit or cancel its decision to register a pesticide on its own initiative at any time if it appears to the EPA that the pesticide causes unreasonable adverse effects on human health or the environment, the pesticide's labeling is no longer adequate, or the pesticide or its labeling otherwise no longer meet the requirements for registration. *See* 7 U.S.C. § 136d(b). In addition, FIFRA requires the EPA to conduct a robust scientific review of each registered pesticide at least every 15 years to ensure that each pesticide can carry out its intended functions without creating unreasonable adverse effects to human health

and the environment based on updated scientific data. *See* 7 U.S.C. § 136a(g). The EPA has a comprehensive process for reviewing previously registered pesticides, after which the EPA issues its determination regarding whether the pesticide continues to meet FIFRA safety standards. *See* 40 C.F.R. §§ 155.23–.58. If the EPA finds that a pesticide does not satisfy the FIFRA safety standard, EPA may initiate cancellation proceedings to rescind a pesticide's registration, 7 U.S.C. §§ 136a(g)(1)(A)(v), 136d(b); 40 C.F.R. § 155.40(a)(2), or may require mitigation measures to reduce risk to acceptable levels, *see* 40 C.F.R. § 155.58.

2. FIFRA's and the EPA's Strict Labeling Requirements for Pesticides

Under FIFRA, a pesticide may not be registered unless the EPA determines that its "labeling . . . compl[ies] with the requirements of [FIFRA]." 7 U.S.C. § 136a(c)(5)(B). Based on its safety assessment, the EPA may require a pesticide's labeling to feature specific statements concerning health and safety, such as "human hazard" or "precautionary statements" to convey warnings about potential health risks and mitigation actions, 40 C.F.R. §§ 156.60–.70; requirements for personal protective equipment, 40 C.F.R. § 156.212; detailed application directions, 40 C.F.R. § 156.10(i); or designations for use restricted to "certified applicators," 40 C.F.R. § 156.10(j)(2)(i)(B).

FIFRA prohibits the sale or distribution of any pesticide that has been "misbranded," 7 U.S.C. § 136j(a)(1)(E), which the statute defines as, among other things, a pesticide label that "does not contain a warning or caution statement which . . . is adequate to protect health and the environment," or "bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." 7 U.S.C. § 136(q)(1). It is unlawful for any person to distribute or sell a pesticide "if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration," 7 U.S.C. § 136j(a)(1)(B), including the statements made in the labeling approved during the pesticide's registration, *see* 7 U.S.C. § 136a(c)(1)(C) (requiring a registration applicant to provide a "complete copy of the labeling" as part of its statement of claims). It is also unlawful for any person "to use any registered pesticide in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G).

"Once a pesticide is registered and its proposed label is approved by the EPA, then [EPA regulation] prohibits the distribution or sale of the pesticide with a modified label, unless and until an application for amended registration is submitted and approved." *Schaffner v. Monsanto Corp*., 113 F.4th 364, 382 (3d Cir. 2024); *see also* 40 C.F.R. § 152.44(a) ("Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration . . . . If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold."). Only "minor modifications" to a pesticide's labeling may be made without prior EPA approval. *See* 40 C.F.R. § 152.46. Any changes to the information stated in a pesticide label's "precautionary statement"—including the addition of a new health hazard—does not qualify as a minor modification and, thus, cannot be made unless and until an application for amended registration is submitted to and approved by the EPA. *See Schaffner*, 113 F.4th at 383–84. A person who violates FIFRA's requirements, including those related to pesticide labeling, risks civil and criminal penalties, stop-sale orders, and proceedings to seize the pesticide. *See* 7 U.S.C. §§ 136l, 136k.

Pursuant to 7 U.S.C. § 136v(b), no state shall "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b). "Congress enacted section 136v(b) to ensure that pesticide labeling requirements would be uniform across the nation." *See Schaffner*, 113 F.4th at 392 (citation omitted). Thus, state-law pesticide labeling requirements, including state-law failure to warn products liability claims, are expressly preempted to the extent they are "in addition to or different from the requirements imposed under FIFRA." *Id.* at 371.

The EPA and State Agencies Have Repeatedly Determined That Roundup's Active Ingredient, Glyphosate, Is Not Likely Carcinogenic

The EPA first registered glyphosate, the active ingredient in Roundup, for use as a pesticide in 1974. *See Schaffner*, 113 F.4th at 373. Over the past several decades, the EPA has continually evaluated the scientific evidence on glyphosate and repeatedly approved the use of glyphosate as a pesticide, each time concluding that it does not cause unreasonable adverse effects on human health and is not likely to be carcinogenic to humans. *See id.*; *see also Nat'l Ass'n of Wheat Growers v. Zeise*, 309 F. Supp. 3d 842, 852, 852 n.13 (E.D. Cal. 2018). After a robust review of scientific studies, in 1991, the EPA specifically classified glyphosate as a chemical for which there exists "evidence of non-carcinogenicity for humans." *See Schaffner*, 113 F.4th at 373. In every decade since, the EPA has reviewed the updated scientific data on glyphosate and reached the same conclusion: that glyphosate is unlikely to cause cancer in humans. *See id.*; *see also Zeise*, 309 F. Supp. 3d at 852, 852 n.13. Currently, the EPA classifies glyphosate as "not likely to be carcinogenic to humans," EPA Off. of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, at 144 (Dec. 12, 2017),[1] meaning that "the available data are considered robust for deciding that there is no basis for human hazard concern," *id.* at 140.

In 2015, a working group of the International Agency for Research on Cancer ("IARC"), an agency of the World Health Organization, issued a report (the "2015 IARC Report") that classified glyphosate as a "Group 2A" agent, meaning that, in IARC's view, glyphosate is "probably carcinogenic to humans." *See*, at 1 (Mar. 20, 2015), https://www.iarc.who.int/wp-content/uploads/2018/07/MonographVolume112-1.pdf. The 2015 IARC Report states that this conclusion is based on "*limited evidence of carcinogenicity* in humans" and "*sufficient evidence of carcinogenicity* in experimental animals." *See id.* IARC's classification reflects a "hazard" assessment—meaning that IARC considered whether glyphosate as a chemical agent is capable of causing cancer under any circumstances, without examining whether any "risk" exists that it actually does so in real-world conditions. *See IARC Monographs on the Identification of Carcinogenic Hazards to Humans: Preamble*, IARC, at 2 (amended 2019), https://monographs.iarc.who.int/wp-content/uploads/2019/07/Preamble-2019.pdf.

Since the 2015 IARC Report was issued, "EPA scientists have performed an independent evaluation of available data . . . to reexamine the carcinogenic potential of glyphosate and concluded that glyphosate is 'not likely to be carcinogenic to humans.'" Aug. 7, 2019 Ltr. from Michael L. Goodis, Director, Registration Div., EPA Pesticide Programs, at 1, https://www.epa.gov/sites/default/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf. In coming to this conclusion, the EPA "considered a more extensive dataset than

[1] This paper can be downloaded at https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0073.

IARC, including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review." *Id.* As the EPA has repeatedly determined that glyphosate is not likely to cause cancer in humans, it does not require a cancer warning on glyphosate labeling and, to the contrary, would consider the addition of a cancer warning on glyphosate labeling to be a "false and misleading statement" that constitutes misbranding in violation of 7 U.S.C. § 136(q)(1)(A). *See id.* at 1–2.

State agencies across the country have also reviewed glyphosate's potential carcinogenic risk and determined that glyphosate does not likely cause cancer in humans and labeling for glyphosate does not require a cancer warning to protect human health. In particular, every two years the Florida Department of Agriculture and Consumer Services (FDACS) reviews scientific data regarding glyphosate's potential health risk, among other information, during its biennial registration renewal review for Roundup. *See* § 487.041, Fla. Stat. (setting forth the Florida Pesticide Law's requirements for pesticide registration and biennial registration renewal); *see also Ezcurra v. Monsanto Co*., No. 9:20-CV-80524, 2020 WL 5491428, at *4–*5 (S.D. Fla. Aug. 7, 2020) (noting that Roundup is registered with FDACS and, thus, must meet Florida law requirements for registration and registration renewal). During the registration and registration renewal process, FDACS completes public health and environmental assessments of the pesticide and reviews "scientific evidence" showing "that the pesticide will not cause any unreasonable adverse effects on public health or the environment." *See* Fla. Admin. Code R. 5E-2.031. FDACS also reviews the pesticide's labeling, *see* § 487.041(1)(a), Fla. Stat., which, among other things, must contain all warnings "adequate to prevent injury to living humans and other vertebrate animals," § 487.025(1)(d), Fla. Stat. Thus, through Roundup's registration and registration renewals, FDACS has repeatedly determined that "the manufacturing of Roundup utilizing glyphosate as an active ingredient is specifically permitted by federal and state law," and "the language contained on Roundup's label (without any cancer warning)," *see Ezcurra*, 2020 WL 5491428, at *5, "adequately warns the public of risks associated with using the product, *id.* at *4.

Despite the EPA's Repeated Determinations That Glyphosate Is Not Likely Carcinogenic, the 2015 IARC Report Has Made Companies a Target for Product Liability Lawsuits Alleging that Exposure to Roundup and Similar Pesticides Causes Cancer

Despite the EPA's repeated determinations that glyphosate is not likely carcinogenic and does not require a cancer warning, the 2015 IARC Report made companies selling or applying Roundup targets for product liability lawsuits alleging that exposure to Roundup caused the plaintiffs to contract cancer. *See Schaffner*, 113 F.4th at 373–74; *see also In re: Roundup Products Liab. Litig.*, 214 F. Supp. 3d 1346, 1347–48 (J.P.M.L. 2016) (transferring lawsuits filed in federal courts across the country alleging that Monsanto's failure to warn of glyphosate's carcinogenic risk caused the plaintiffs to contract non-Hodgkin's lymphoma to a multidistrict litigation for pretrial proceedings). These lawsuits predominantly involve failure to warn products liability claims, namely, claims that a product's lack of adequate warnings rendered the product unreasonably dangerous and caused the plaintiff's injury. Specifically, the plaintiffs in the Roundup lawsuits claim that the defendant company failed to warn that Roundup's active ingredient, glyphosate, causes cancer, and this failure to warn caused the plaintiffs to be exposed to glyphosate and contract cancer. Some of the Roundup lawsuits have also alleged that Roundup is defectively designed because its use of glyphosate is unreasonably dangerous. The failure to warn and design defect claims in the Roundup lawsuits are based on both strict liability—where

the defendant may be liable regardless of whether it exercised all possible care in the preparation and sale of the product—and negligence—where the defendant breached a duty of reasonable care in the preparation or sale of the product.

Johnson v. Monsanto Co. was the first of the Roundup lawsuits to proceed to trial. *See Johnson v. Monsanto Co*., 266 Cal. Rptr. 3d 111, 120 (Ct. App. 2020), *as modified on denial of reh'g* (Aug. 18, 2020). The jury in that case found Monsanto liable for defective design, strict liability failure to warn, and negligent failure to warn, and awarded the plaintiff $39.3 million dollars in compensatory damages and $250 million dollars in punitive damages (which was reduced on appeal to $10,253,209 in compensatory damages and $10,253,209 in punitive damages). *See id.* at 120, 136.

Shortly thereafter, *Hardeman v. Monsanto Co*. became the first bellwether trial of the federal cases consolidated to multidistrict litigation for pretrial proceedings. *See Hardeman v. Monsanto Co*., 997 F.3d 941, 950 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022). At that trial, a jury found Monsanto liable for failing to warn of Roundup's carcinogenicity and awarded compensatory damages of over $5 million and punitive damages of $75 million (the punitive damages award was reduced by the court to $20 million). *Id.*

In both *Johnson* and *Hardeman*, Monsanto argued that the plaintiffs' claims were legally barred because they are preempted by FIFRA. Specifically, Monsanto argued that the California-law failure to warn claims (which were asserted in both cases) were expressly preempted because those claims impose "requirements for [Roudup's] labeling or packaging [that are] in addition to or different from those required under [FIFRA]." *See* 7 U.S.C. § 136v(b). Monsanto also argued that the failure to warn claims were preempted under the doctrine of implied conflict preemption because it would be impossible for Monsanto to comply with both FIFRA and labeling requirements imposed by the state-law claims. *See, e.g.*, *Hardeman*, 997 F.3d at 950. Indeed, the failure to warn claims would require Monsanto to include a warning on Roundup's labeling that glyphosate exposure likely causes cancer, whereas, the EPA, pursuant to its authority under FIFRA, does not require or permit a cancer warning on Roundup's labeling. *See* Aug. 7, 2019 Ltr. from Michael L. Goodis, Director, Registration Div., EPA Pesticide Programs, at 1–2. As to the design defect claim asserted in *Johnson*, Monsanto argued that the claim was preempted under implied conflict preemption because it would be impossible for Monsanto to comply with both FIFRA and state-law requirements imposed by the design defect claims. *See* Appellant's Opening Br., *Johnson v. Monsanto Co*., Nos. A155940, A156706, 2019 WL 1871152, at *64–*65 (Cal. App. 1st Dist.). Namely, Monsanto argued that it was barred by EPA regulations from making changes to the active or inert ingredients of its Roundup pesticide product—as would be required under the plaintiff's design defect claim—without first obtaining EPA approval. *See id.*

The trial courts in both *Johnson* and *Hardeman* rejected Monsanto's preemption arguments, holding that neither the failure to warn nor design defect claims were preempted by FIFRA. *See Johnson*, 266 Cal. Rptr. 3d at 114; *Hardeman*, 997 F.3d at 950. The trial courts' holdings denying Monsanto's preemption defenses were upheld by the California First District

Court of Appeal, *see Johnson*, 266 Cal. Rptr. 3d at 114,[2] and Ninth Circuit Court of Appeals, *see Hardeman*, 997 F.3d at 950. The Ninth Circuit determined that FIFRA did not preempt the failure to warn claims because the EPA's approvals of Roundup's labeling during the pesticide's registration and re-registrations, including the lack of cancer warning, were merely "*prima facie evidence* of FIFRA compliance." *Hardeman*, 997 F.3d at 956 (citing 7 U.S.C. § 136a(f)(2)). The court reasoned that the EPA's letter stating that the addition of a cancer warning to Roundup's labeling would constitute misbranding was a policy opinion that "do[es] not carry the force of law," and, thus, it was not impossible for Monsanto to add the cancer warning without violating FIFRA. *See id.* at 957–60.

Following the Ninth Circuit's decision in *Hardeman*, the issue of whether state-law failure to warn claims based on the failure to include a cancer risk warning on Roundup's labeling is preempted by FIFRA has been addressed by two other circuits. *See Carson v. Monsanto Co*., 92 F.4th 980 (11th Cir. 2024); *Schaffner*, 113 F.4th 364. The Eleventh Circuit agreed with the Ninth Circuit, holding that the plaintiff's failure to warn claims were neither expressly nor impliedly preempted by FIFRA. *See Carson*, 92 F.4th at 999. The court held that the EPA's registrations and re-registrations of Roundup's labeling did not carry the force of law and, thus, could not preempt state-law requirements that differed from those approvals. *Id.* at 990–93. The court stated that Monsanto could not show that complying with the state-law requirement of including a cancer warning on Roundup's labeling would irreconcilably conflict with the FIFRA regime because the EPA's "repeated approvals of a label without a cancer warning do not mean the Agency necessarily would have rejected a label with a cancer warning." *See id.* at 997–98.

The Third Circuit disagreed with the Ninth and Eleventh Circuits, holding that the plaintiff's state-law failure to warn claims were expressly preempted by FIFRA: "Because regulations promulgated to implement FIFRA require the health warnings on a pesticide's label to conform to the proposed label approved by the EPA during the registration process (the 'Preapproved Label'), and because during Roundup's registration process the EPA approved proposed labels omitting a cancer warning following an extensive review of scientific evidence concerning Roundup's possible carcinogenicity, we conclude that the alleged state-law duty to include the Cancer Warning on Roundup's label . . . imposes requirements that are different from those imposed under FIFRA, and that it is therefore preempted by FIFRA." *Id.* Accordingly, there is currently a circuit-split regarding whether FIFRA preempts state-law failure to warn claims alleging that Roundup's labeling should warn of the risk that exposure to glyphosate causes cancer.

The eight-figure jury verdicts in *Johnson* and *Hardeman*, and the lack of preemption defense in many jurisdictions outside of the Third Circuit (including Florida), have opened the floodgates of litigation against not only the manufacturers of Roundup pesticides, but distributors and others whose only action was to distribute or sell the allegedly defective product. Indeed, there has been approximately 177,000 claims asserted against Monstanto and its successors, and they have paid billions of dollars in settlements and verdicts. *See* Managing the Roundup Litigation,

[2] The California Court of Appeal's affirmance "turn[ed] on the lack of a developed factual record" and, consequently, that portion of the court's decision is not certified for publication under California court rules. *Johnson*, 266 Cal. Rptr. 3d at 114 fns.

bayer.com, https://www.bayer.com/en/managing-the-roundup-litigation#:~:text=3.,Safety%20study%20webpage: (last visited Jan. 6, 2025).

The Florida Legislature Should Pass Sensible Legislation Exempting Manufacturers, Distributors, Sellers, and Applicators of Pesticides from Failure to Warn and Design Defect Actions Involving Pesticides that Meet Federal and State Safety and Labeling Requirements.

The Roundup lawsuits have spiraled out of control, threatening the affordable use of Roundup and other essential pesticide products by Florida farmers and others in the agricultural industry. Florida's farmers depend on Roundup and other pesticides to manage pests and control plant diseases that can destroy crops and threaten a reliable and affordable food supply. Pesticide manufacturers, distributors, sellers, and applicators should not face astronomical litigation risk for products liability claims involving pesticides that comply with FIFRA's comprehensive requirements and have been determined by both the EPA and FDACS to have no unreasonable risk to human health and the environment. Such litigation risk reduces farmers' ability to protect crops and maintain important conservation practices, and threatens food availability and affordability across the nation.

Accordingly, to protect Florida's food supply and ensure the uniform, science-based requirements of FIFRA, the EPA, and FDACS are applied to the use of agricultural pesticides in Florida, the Florida Legislature should create the following sensible exemption from failure to warn and design defect products liability actions for the distribution, sale, or application of agricultural pesticide products that comply with FIFRA and Florida regulatory requirements:

> No manufacturer, distributor, seller, or applicator of an agricultural pesticide product may be liable for a civil action for damages based on a products liability theory if, at the time of the alleged injury, the product was registered by both the United States Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 et seq., and the Florida Department of Agriculture and Consumer Services pursuant to the Florida Pesticide Law, §§ 487.011–.175; and
>
> (a) the claimant alleges that the product's labeling should have contained any warning, instruction, or other information in addition to or different from the warnings, instructions, or other information contained in the product's labeling approved by the United States Environmental Protection Agency and the Florida Department of Agriculture and Consumer Services at the time of the alleged injury; or
>
> (b) the claimant alleges that the product was defectively designed because it is carcinogenic and, at the time of the alleged injury, that allegation was inconsistent with the conclusions of a carcinogen risk assessment of the product performed by the United States Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 et seq.