IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

OTIS LINDELL CHAPMAN AND KIM CHAPMAN,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	CIVIL ACTION NO. H-22-738
	§	
MONSANTO COMPANY,	§	
	§	
Defendant.	§	

MEMORANDUM AND OPINION

Roundup is an herbicide used to kill weeds. Glyphosate is the active ingredient in Roundup. In 1985, the Environmental Protection Agency briefly classified glyphosate as a possible human carcinogen after a study found that "glyphosate was oncogenic in male mice." Since then, however, the EPA has repeatedly stated that glyphosate is unlikely to be carcinogenic to humans. The EPA, which registers Roundup and periodically reviews and reregisters glyphosate as a condition for Monsanto to distribute and market Roundup, has not required Monsanto to include a warning on Roundup that glyphosate may cause cancer in humans.

In 2015, the International Agency for Research on Cancer classified glyphosate as "probably carcinogenic to humans," based on studies that found an association between glyphosate exposure and non-Hodgkin's lymphoma, a cancer that affects white blood cells. That classification triggered state and federal lawsuits against Monsanto brought by tens of thousands of individuals with non-Hodgkin's lymphoma. Many of those cases were consolidated into a multi-district litigation in the Northern District of California. The MDL court has handled discovery, held *Daubert* hearings for expert witnesses, and decided pretrial dispositive and nondispositive motions. The court also held a bellwether trial that resulted in a jury award to the plaintiff of

$5,066,667 in compensatory damages and $75,000,000 in punitive damages, which were later reduced to $20,000,000. Many cases in the MDL have settled. This case has not. The MDL court remanded this case in April 2022.

Otis Lindell Chapman used two Roundup products—Roundup® Weed & Grass Killer Concentrate and Roundup® Ready-to-Use Weed & Grass Killer—intermittently for 20 years, from 1987 to 2018, around his home's sidewalk, driveway, and trees. (Docket Entry No. 72-2, at 12–13). In 2003, he was diagnosed with non-Hodgkin's lymphoma. Chapman was successfully treated for the cancer, but after a long period of remission, it returned. Chapman alleges that the Roundup products, and Monsanto's omissions or actions in designing Roundup, failing to warn about its carcinogenic risks, and mispresenting or breaching warranties relating to safety, caused his non-Hodgkin's lymphoma. He asserts state-law claims of design defect, failure to warn, negligence, and breach of express and implied warranty. His wife, Kim Chapman, has also sued for loss of consortium.

Monsanto moved for summary judgment under a Texas statute, §82.008(c) of the Texas Civil Practice & Remedies Code. Section 82.008(c) provides a rebuttable presumption that a defendant is not liable for a plaintiff's injuries related to "some aspect of the formulation, labeling, or design of a product" that was approved or licensed for sale by a federal agency. Tex. Civ. Prac. & Rem. Code § 82.008(c). A plaintiff can rebut the presumption of nonliability by showing that "the standards or procedures used in a particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage." *Id.* § 82.008(c)(1). A plaintiff can also rebut the presumption by showing that the defendant, "before or after pre-market approval or licensing of the product, withheld from or misrepresented to the government

or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury." *Id.* § 82.008(c)(2).

Monsanto argues that this Texas law, a tort-reform product, precludes its liability on the Chapmans' product-liability claims, because the EPA repeatedly approved and registered Roundup and its active ingredient, glyphosate, for distribution and sale. Monsanto argues that it is entitled to the presumption against liability under § 82.008(c), and that the Chapmans have not come forward with record evidence rebutting the presumption. Monsanto also argues that federal law (specifically, the Federal Insecticide, Fungicide, and Rodenticide Act) preempts the Chapmans' from proving under § 82.008(c)(2) that Monsanto is liable because it "withheld from or misrepresented" material and relevant information about Roundup products to the EPA.

The Chapmans oppose the motion. The Chapmans initially argued that Monsanto was not entitled to the presumption against liability because the EPA has never approved the composite Roundup product, as opposed to its individual ingredients (like glyphosate). The court requested supplemental briefing on whether the EPA has approved the specific Roundup products at issue in this litigation, and Monsanto provided evidence that EPA had registered the products at issue. The Chapmans have abandoned this argument. (*See* Docket Entry No. 74).

The Chapmans instead argue that even if Monsanto is entitled to the presumption, the presumption is rebutted because there is evidence that the EPA's approval process was inadequate to protect the public from unreasonable risk of injury, and there is evidence that Monsanto repeatedly withheld relevant information about, and misrepresented the risks of, Roundup to the EPA. Monsanto responds by challenging the evidence of inadequate standards and procedures used to register Roundup on which the Chapmans rely, and by arguing that federal law preempts the Chapmans' claim of "fraud on the EPA."

Based on the motion, the briefs, the supplemental briefs, the record, the oral argument, and the applicable case law, the court denies Monsanto's motion for summary judgment. The reasons are set out below.

I. The Summary Judgment Standard

"Summary judgment is appropriate only when 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Shepherd ex rel. Est. of Shepherd v. City of Shreveport*, 920 F.3d 278, 282–83 (5th Cir. 2019) (quoting Fed. R. Civ. P. 56(a)). "A material fact is one that might affect the outcome of the suit under governing law," and "a fact issue is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Renwick v. PNK Lake Charles, LLC*, 901 F.3d 605, 611 (5th Cir. 2018) (citations and quotation marks omitted). The moving party "always bears the initial responsibility of informing the district court of the basis for its motion," and identifying the record evidence "which it believes demonstrate[s] the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

When the moving party has met its Rule 56(c) burden, the nonmoving party cannot survive a summary judgment motion by resting on the mere allegations of its pleadings. The nonmovant must identify specific evidence in the record and articulate how that evidence supports that party's claim. *Willis v. Cleco Corp.*, 749 F.3d 314, 317 (5th Cir. 2014). "A party cannot defeat summary judgment with conclusory allegations, unsubstantiated assertions, or only a scintilla of evidence." *Lamb v. Ashford Place Apartments LLC*, 914 F.3d 940, 946 (5th Cir. 2019) (citation and quotation marks omitted). In deciding a summary judgment motion, "the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his or her favor." *Waste Mgmt. of La.,*

LLC v. River Birch, Inc., 920 F.3d 958, 972 (5th Cir. 2019) (alterations omitted) (quoting *Tolan v. Cotton*, 572 U.S. 650, 656 (2014)).

II. Analysis

A. Waiver

The Chapmans first argue that Monsanto's motion for summary judgment should be denied, because Monsanto cannot raise new arguments on summary judgment after the dispositive motion deadline has passed. This argument is without merit, because this court already granted Monsanto's motion for leave to file for summary judgment. This court did not explicitly state its reasons on the record for granting the motion, however, and so clarifies those reasons now.

In October 2016, the Judicial Panel on Multidistrict Litigation created an MDL in the Northern District of California to coordinate for pretrial proceedings federal court cases in which plaintiffs alleged that Roundup caused their non-Hodgkin's lymphoma. *In re Roundup Liability Litig.*, 214 F. Supp. 3d 1346 (J.P.M.L. 2016). The Chapmans filed this case in the Southern District of Texas in December 2019, and the MDL Panel transferred the case to the MDL in February 2020. This case became part of the "third wave" of cases in the MDL.

The parties in the "Wave 3" cases completed discovery and filed dispositive motions in the MDL court in September 2021. Monsanto moved for summary judgment based on a different provision of the Texas Product Liability Act, § 82.008(a). Monsanto argued that it was entitled to a presumption of no liability under § 82.008(a) on the Chapmans' claims of strict-liability design defect, failure to warn, negligence, breach of express and implied warranty, and loss of consortium. *In re Roundup Prods. Liab. Litig.*, Case No. 3:20-cv-01277-CV, Docket Entry No. 14, at 6 (N.D. Cal. Sept. 21, 2021). Section 82.001(a) provides that:

> there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or

> design of a product if the product manufacturer or seller establishes that the product's formula, labeling, or design complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, that were applicable at the time of manufacture and that governed the product risk that allegedly caused harm.

Tex. Civ. Prac. & Rem. Code § 82.008(a).

Monsanto argued that "Roundup's design, formulation, and labeling have been, at all times, subject to mandatory standards and regulations promulgated by the U.S. Environmental Protection Agency," and that because "Roundup has been, and remains, fully compliant with EPA governance in both its glyphosate formulation and labeling," Monsanto was entitled to an rebuttable presumption of non-liability under the Act.

The MDL court denied Monsanto's motion for summary judgment, holding that Monsanto had moved under the wrong provision of the Texas Product Liability Act. Instead of moving under § 82.001(a) of the Act, which provides a presumption of no liability for products that comply with mandatory safety standards or regulations, Monsanto should have moved under § 82.001(c), which provides a presumption of no liability for products that have received a federal agency's approval or license for sale. *See In re Roundup Prods. Liab. Litig.*, MDL No. 2741, 2021 WL 6125536 (N.D. Cal. Dec. 28, 2021). Section (c) states that:

> there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant allegedly caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirement with respect to pre-market licensing or approval, and that after full consideration of the product's risks and benefits the product was approved or licensed for sale by the government or agency.

Tex. Civ. Prac. & Rem. Code Ann. § 82.008(c).

After denying summary judgment, the MDL court suggested that this case be remanded to the Southern District of Texas for trial, because discovery in this case was complete, the dispositive motion deadline had passed, and the case had not settled following the MDL court's denial of summary judgment. The MDL court stated that the only remaining issue for this court to handle, other than trial, were motions *in limine* that the MDL court had denied without prejudice so that the parties could refile them before this court.

This case was transferred back to the Southern District of Texas in March 2022, and assigned to this court. This court held a status conference on April 12, 2022. At that status conference, Monsanto moved for leave to file another motion for summary judgment, this time under § 82.008(c) of the Texas Product Liability Act. This court granted the motion, and ordered Monsanto to promptly file the motion.

An MDL court's scheduling order is the law of the case. *See* Charles Alan Wright & Arthur R. Miller, *Law of the Case Doctrine and the Effect of Transfer and Remand on Choice of Law*, 15 Fed. Prac. & Proc. Juris. § 3867 (4th ed). If a plaintiff or defendant wishes to file a motion for summary judgment in the transferee court after the dispositive motion deadline has passed, the party must move for leave to file, and must show good cause. *See, e.g.*, *George v. Johnson & Johnson*, Case No. 3:12-CV-369, 2021 WL 5029471, at *3 (N.D. Ind. 2021) (denying the defendants' motion for leave to file a motion for summary judgment after remand from the MDL court). To decide whether Monsanto has good cause to file this motion for summary judgment after the dispositive motion deadline has passed, this court weighs efficiency and equity concerns.

Equity weighs in favor of the Chapmans. There is no reason why Monsanto could not have moved in the MDL court for summary judgment under § 82.008(c), and its failure to do so was its own. The issue that Monsanto raises now on summary judgment is precisely the type of issue—

one that could apply to all Roundup cases raising products liability claims under Texas law—that is best handled uniformly by the MDL court.[1]

Efficiency, however, weighs in favor of Monsanto. This issue—whether the Texas Product Liability Act precludes liability on the Chapmans' claims—is one that will need to be addressed at some point, if not now, then on a motion for judgment as a matter of law at trial under Rule 50(a).

This court prioritizes the time and effort of the jury. This case is set for trial in February 2023. Deciding this motion for summary judgment now, as opposed to later—on a tighter timeline—at trial, prejudices neither party. No delay in trial will occur. And even if summary judgment is not granted, familiarity and understanding of the issues in advance of trial is helpful to the court and the litigants. For this reason, the court granted the motion for leave to file this motion for summary judgment, and now considers the motion on the merits.

B. The Texas Product Liability Act

Texas law includes a presumption that a manufacturer is not liable in a products-liability action if a product at issue was

(1) subject to licensing or approval by the federal government or a federal agency;

(2) that the manufacturer complied with all of the relevant federal procedures and requirements for licensing and approval; and

(3) that the product was approved after full consideration of the product's risks and benefits.

Tex. Civ. Prac. & Rem Code § 82.008(c).

[1] The court and the parties are aware of only one other case from the MDL involving Texas law that has been remanded from the MDL. That is *Koen v. Monsanto Company*, Case No. 1:22-cv-00209-RP (W.D. Tex.). The court also asked the parties whether they were aware of any other states that have similar statutes to the Texas statute at issue here. The parties were not aware of other identical or similar statutes. The parties believe that this court's ruling on the application of the Texas statute to a Roundup case, or even to a federally regulated and licensed product, is one of first impression.

The presumption may be rebutted if the plaintiff establishes that "the standards or procedures used in a particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage," or that the defendant, "before or after pre-market approval or licensing of the product, withheld from or misrepresented to the government or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury." Tex. Civ. Prac. & Rem. Code § 82.008(c)(1), (c)(2).

Monsanto argues that it is entitled to the presumption against liability, that there is no evidence rebutting the presumption, and that the Chapmans are preempted by federal law from rebutting the presumption by proving that Monsanto withheld or misrepresented relevant information regarding Roundup to the EPA. The issues are whether there are factual disputes material to determining whether the presumption applies and, if so, whether it can be rebutted. Both are addressed below.

i. The Presumption Against Liability

Texas law creates a rebuttable presumption against liability for a product manufacturer if its product was "subject to licensing or approval" by a federal agency, after the agency's "full consideration of the product's risks and benefits." Glyphosate—the active ingredient in most Roundup products—is subject to a licensing process by the EPA called "registration" and "re-registration." The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires companies that want to sell or distribute a pesticide in the United States to go through the EPA registration process. *See* 7 U.S.C. § 136a(a); 40 C.F.R. § 152.42. To register a pesticide, an applicant must submit the name of the pesticide; a complete copy of the labeling of the pesticide; the complete formula of the pesticide; and studies and data relating to the safety of the pesticide.

7 U.S.C. § 136a(c); 40 C.F.R. § 152.50. The EPA considers these materials "along with other independent studies to assess the safety of the pesticide and to determine whether it should be registered." *In re Roundup Prods. Liability Litig.*, 2021 WL 6125536, at *1.

The EPA must register a pesticide if it determines that the submitted labeling complies with requirements under FIFRA and determines that the pesticide "will perform its intended function without unreasonable adverse effects on the environment" and "when used in accordance with widespread and commonly recognized practice . . . will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). FIFRA defines "unreasonable adverse effects on the environment" to mean "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). By registering the pesticide, the EPA "provide[s] a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used within the United States." *Nat'l Fam. Farm Coal. v. Envtl.. Prot. Agency*, 966 F.3d 893, 912 (9th Cir. 2020) (citing 7 U.S.C. § 136a(c)).

It is unlawful for a manufacturer to sell a pesticide that is registered but "misbranded." *See* 7 U.S.C. § 136j(a)(1)(E). A pesticide is misbranded if "its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading." *Id.* § 136(q)(1)(A). Manufacturers have an ongoing obligation to ensure that the pesticide's labeling is accurate, truthful, and compliant with FIFRA's labeling requirements. *See Bates v. Agrosciences LLC*, 554 U.S. 431, 438 (2005). Pesticide manufacturers can seek approval to amend the pesticide's label, *see* 7 U.S.C. § 136a(f)(2), and manufacturers "have a duty to report incidents involving a pesticide's toxic effects that may not be adequately reflected in its label's warnings." *Pilliod v. Monsanto Co.*, 67 Cal. App. 591, 614, 282 Cal. Rptr. 3d 679, 699 (2021). In 2007,

Congress added a process called "registration review," instructing the EPA to "periodically review[]" pesticide and herbicide registrations every fifteen years. 7 U.S.C. § 136a(g)(1)(A). "The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects." (Docket Entry No. 61-11, at 4).

The EPA first registered glyphosate in 1974 and has reregistered glyphosate several times since. (*See, e.g.*, Docket Entry No. 61-4 (concluding on reregistration in September 1993 "that the use of glyphosate-based herbicides in accordance with label directions would 'not pose unreasonable risks or adverse effects to humans or the environment'")); *see also Hardeman v. Monsanto Co.*, 997 F.3d 941, 951 (9th Cir. 2021) (discussing the EPA's reevaluation of glyphosate). The EPA's first registration review for glyphosate is due on October 1, 2022.

EPA also reviews and registers pesticide and herbicide products, including the Roundup-branded products.[2] (*See* Docket Entry No. 71, at 2); *Ctr. for Biological Diversity v. Envtl. Prot. Agency*, 847 F.3d 1075, 1080 (9th Cir. 2017) ("The Federal Insecticide, Fungicide, and Rodenticide Act . . . charges the Environmental Protection Agency . . . with the obligation to register and reregister pesticide active ingredients and pesticide products."). A "pesticide product" is defined as "a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed and sold." 40 C.F.R. § 152.3.

[2] Monsanto's motion for summary judgment did not initially explain, in detail, EPA's process for approving pesticide products. This court requested supplemental briefing asking for further explanation on whether "the EPA has licensed and approved Roundup itself." (Docket Entry No. 70, at 2). Monsanto responded with further details about EPA's registration process. (Docket Entry No. 71). The Chapmans responded to the request for further briefing, but did not respond to the court's inquiry. The Chapmans' response argues that the approval does not give rise to the presumption under § 82.008(c)(1), and that any presumption that arises can be rebutted under § 82.008(c)(2). (*See* Docket Entry No. 74).

The same standards applicable to pesticides, such as glyphosate, apply to pesticide products, such as the Roundup-branded products; however, the review of the pesticide product is focused on the end-use formulation rather than just the active ingredient. The review is also premised on EPA's prior review and registration of the pesticide product's active ingredient. "Any person seeking to obtain a registration for a new pesticide product must submit an application for registration," which "must be approved by the [EPA] before the product may legally be distributed or sold." 40 C.F.R. § 152.42; *see also Nat. Res. Def. Council v. Envtl. Prot. Agency*, 38 F.4th 34, 40 (9th Cir. 2022) ("A pesticide product may not be distributed or sold in the United States until EPA has issued a registration, which functions as a license setting forth the conditions under which the pesticide may be sold, distributed, and used."). That application requires the pesticide-product manufacturer to submit a confidential statement of the product's formula, including "each component [ingredient] in [the] formulation" and the percentage amount of that ingredient contained in the formulation. (*See* Docket Entry No. 72-1, at 2).

The EPA will register a pesticide product containing a new active ingredient only after "determin[ing] that the product will perform its intended function without unreasonable adverse effects on the environment . . . when used in accordance with widespread and commonly recognized practice," and "that the product is not misbranded." 40 C.F.R. § 152.112(e), (f). The EPA will "conditionally" register products that contain active ingredients already approved by the EPA if the agency concludes that:

1. the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; and

2. approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment.

EPA, *When Can EPA Grant a Conditional Registration?*, https://www.epa.gov/pesticide-registration/conditional-pesticide-registration#epa-grant (last visited Aug. 28, 2022). "While a conditional registration might mean the initial registration is more prompt than it otherwise would be, . . . the 'applicant seeking conditional registration' must submit the same 'data as would be required to obtain' unconditional registration." (Docket Entry No. 78, at 3 (quoting 7 U.S.C. § 136a(c)(7)(A)).[3]

The two products that Otis Chapman allegedly used were both registered by the EPA. Roundup Weed & Grass Killer Concentrate Plus was first conditionally registered by the EPA on October 31, 2001. (Docket Entry No. 72-3; Docket Entry No. 78). The registration notice instructed Monsanto to "[a]dd the phrase 'EPA Registration No. 71995-29' before . . . releas[ing] the product for shipment." (Docket Entry No. 72-3, at 2). Roundup Ready-to-Use Weed & Grass Killer was first conditionally registered by the EPA on June 18, 1991. (Docket Entry No. 72-5). Those registrations necessarily required the EPA to consider and conclude that registering the product would not "significantly increase the risk of any unreasonable adverse effect on the environment."

Monsanto has clearly demonstrated that the Roundup products and the active ingredient, glyphosate, have been "subject to licensing or approval by the federal government or a federal agency." But Monsanto has not met its burden of showing the absence of factual disputes material to determining to whether it "complied with all of the relevant federal procedures and requirements with respect to pre-market licensing and approval," as necessary to be entitled to the presumption. And the Chapmans have identified facts that might support an inference that the EPA's application

[3] At the August 25, 2022, hearing, the Chapmans agreed with Monsanto that there is no relevant distinction between conditional and unconditional registration for the purpose of deciding whether the rebuttable presumption applies.

of its procedures and standards to the registration and reregistration of glyphosate and Roundup-branded products were inadequate to protect the public's safety.

To be entitled to the presumption against liability, Monsanto must show that it "complied with all of the relevant procedures and requirements for licensing and approval." Monsanto argues that "it is undisputed that Monsanto, at all relevant times, has been in compliance with the EPA's mandatory registration and review process," as "evidenced by EPA's repeated approval of the product." (Docket Entry No. 61, at 6). But registration does not automatically mean compliance with relevant procedures and requirements. The Federal Insecticide, Fungicide, and Rodenticide Act states that "registration of a pesticide shall be *prima facie evidence* that the pesticide, its labeling and packaging comply with the registration provisions of [FIFRA]." 7 U.S.C. § 136a(f)(2) (emphasis added). "Prima facie evidence is not conclusive proof." *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016).

The Chapmans dispute that Monsanto complied with the relevant procedures and requirements. The Chapmans argue that Monsanto violated § 6(a)(2) of FIFRA, 40 C.F.R. § 159.158, which states:

> (a) General. Information which is reportable under this part must be submitted if the registrant possesses or receives the information, and the information is relevant to the assessment of the risks or benefits of one or more specific pesticide registrations currently or formerly held by the registrant. Information relevant to the assessment of the risks or benefits also includes conclusion(s) or opinion(s) rendered by a person who meets any of the following:
>
> (1) Who was employed or retained (directly or indirectly) by the registrant, and was likely to receive such information.
>
> (2) From whom the registrant requested the opinion(s) or conclusion(s) in question.
>
> (3) Who is a qualified expert as described in § 159.153(b).

Section 6(a)(2) means that "pesticide manufacturers have a perpetual duty to adhere to FIFRA's labeling requirements and to report any new adverse effects to the EPA." *Carson v. Monsanto Co.*, 39 F.4th 1334, 1338 (11th Cir. 2022). In 1998, the EPA also issued a guidance on Section 6(a)(2), addressing "Expert Opinion Information." That section begins by stating:

> Conclusions or opinions of experts must be submitted under FIFRA 6(a)(2) if the registrant possesses the information and either 1) the information is otherwise reportable under one of the substantive provisions of the rule; or 2) the registrant knows, or should reasonably know, that the information, alone or in conjunction with other information, might raise concerns about the continued registration of a pesticide or about the appropriate terms and conditions of registration of a pesticide. As a general matter, the Agency frequently relies on the "weight of evidence" in making pesticide regulatory decisions, and it considers expert opinion that tends to confirm or validate otherwise reportable information. In this context, expert opinions can play an important role in Agency decision-making.

EPA, *Pesticide Registration Notice 98-3*, at 8 (Apr. 3, 1998), https://www.epa.gov/sites/default/files/2014-04/documents/pr98-3.pdf.

The Chapmans argue that Monsanto had a report from a Monsanto-commissioned expert stating that glyphosate could cause cancer but did not present this evidence to the EPA or seek to amend its label. The Chapmans' relevant summary judgment evidence is summarized below.

In the late 1990s, after four separate studies concluded that glyphosate was possibly genotoxic, Monsanto hired Dr. James M. Parry, a toxicologist specializing in genetic toxicology, to examine the potential genotoxicity of glyphosate and Roundup.[4] (Docket Entry No. 66-3, at 245; *id.*, at 436 (Q: "Monsanto agreed Dr. Parry was an expert in the area, right?" Q: "Yes.")). Dr. Parry was asked to do an "evaluation of the four papers [Monsanto] provided concerning the potential genotoxicity of glyphosate and Roundup." (*Id.*, at 245). Dr. Parry submitted his first

[4] A toxicologist is a scientist who studies the effects of chemical substances on the health of animals and humans. (Docket Entry No. 64-3, at 437). Genotoxic substances damage genetic information in cells, potentially leading to the development of cancers. (*See* Docket Entry No. 66-3, at 172–73, 186–87).

report to Mark Martens, the Toxicology Director at Monsanto Europe, in February 1999. Dr. Parry stated that glyphosate could be genotoxic, and suggested a battery of tests that Monsanto could conduct on Roundup's genotoxicity. (*Id.*, at 251–53, 262, 267–68). Dr. Parry suggested, for example, that Monsanto conduct "an assessment of the individual components of the Roundup mixture . . . to see if they act synergistically when they are together." (*Id.*, at 420). Dr. Parry concluded his report stating, "If the genotoxic activity of glyphosate and its formulations is confirmed it would be advisable to determine whether there are exposed individuals and groups within the human population. If such individuals can be identified then the extent of exposure should be determined and their lymphocytes analysed [*sic*] for the presence of chromosome aberrations." (*Id.*, at 269).

Monsanto did not share Dr. Parry's report or suggestions with the EPA, and Monsanto did not conduct any of Dr. Parry's suggested tests. (*Id.*, at 405–06, 437). In an email discussing Dr. Parry's report, William Heydens—Monsanto's toxicologist—wrote,

> [L]et's step back and look at what we are really trying to achieve here. We want to find/develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox issues arise. My read is that Parry is not currently such person, and it would take quite some time and $$$/studies to get him there. *We simply aren't going to do the studies Parry suggests*. . . . Even if we think we can eventually bring Parry around closer to where we need him, we should be currently looking for a second/back-up genetox support. We have not made much progress and are currently very vulnerable in this area.

(*Id.*, at 271 (emphasis added)).

Mark Martens, another toxicologist at Monsanto, emailed Heydens and Donna Farmer (another Monsanto toxicologist) regarding Dr. Parry's suggestions for further testing. He wrote, in relevant part:

> [I]f somebody came to me and said they wanted to test Roundup I know how I would react—with serious concern. We have to really think about doing

> formulations even if they are not on the market….glyphosate is still in there and could get caught up in some false positive finding.

(*Id*, at 304). The Chapmans argue that this email suggests that Monsanto refused to conduct Dr. Parry's suggested tests "because it believed the tests would reveal that Roundup is genotoxic." (Docket Entry No. 66, at 11).

In 1999—and in parallel with Dr. Parry's review—Monsanto retained another expert, Dr. Gary Williams. Williams, a researcher in the Department of Pathology at New York Medical College, published an article titled, "Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans." (Docket Entry No. 66-3, at 580). That article stated that "under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans." (*Id.*). However, neither Dr. Williams nor any other listed author wrote the article. Monsanto ghostwrote the article. (*See id.*, at 321 (February 2015 email from Heydens to Farmer) ("An option would be to add Greim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000.")). Monsanto then used the article as "an invaluable asset" in "responses to agencies," "Scientific Affairs rebuttals," and "[r]egulator reviews." (*Id.*, at 284). Monsanto did not disclose to the EPA that it ghostwrote the article. The EPA relied on the Williams study in its 2017 evaluation of glyphosate's "carcinogenic potential." *See* EPA Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, at 22, 98, 120 (Sept. 12, 2016).

In 2002, Heydens suggested in an email to Farmer that Monsanto "re-visit" the genotoxicity of Roundup. Heydens noted that "[g]lyphosate is OK but the formulated product (and thus the surfactant) does the damage." (Docket Entry No. 66-3, at 315). Heydens asked, "Can we scale back a repro study to make it budgetarily palatable?" (*Id.*, at 315). The Chapmans

argue that this email suggests that Monsanto knew that Roundup was potentially dangerous. Despite this awareness and Heyden's suggestion for further study, Farmer noted in a 2009 email that Monsanto could not "say that Roundup does not cause cancer [because Monsanto had] not done carcinogenicity studies with Roundup." (*Id.*, at 276). In addition, Monsanto has admitted that it has not done "an epidemiological study to study the association between glyphosate-containing formulations and non-Hodgkin's lymphoma"; "has not conducted a long-term animal carcinogenicity study on glyphosate since 1991"; and "has never conducted a 12-month or longer term animal carcinogenicity study on any surfactants used in glyphosate-based products." (*Id.*, at 33).

This record shows that Monsanto hired an expert over 20 years ago to evaluate whether glyphosate, alone or in combination with other Roundup ingredients, was genotoxic. That expert reviewed legitimate studies showing that glyphosate could be carcinogenic and suggested follow-up studies. Monsanto did not conduct those studies and did not submit the expert's report to the EPA. Monsanto looked for experts who would support its position on glyphosate and, on at least one occasion, ghostwrote an article under the name of its hired expert. Monsanto did not reveal that the article was ghostwritten. Monsanto's own toxicologists considered, at various times, conducting further testing in light of various papers and studies suggesting that glyphosate might cause cancer in mice and humans. Monsanto never conducted any "epidemiological study to study the association between glyphosate-containing formulations and non-Hodgkin's lymphoma."

This evidence creates factual disputes material to determining whether Monsanto violated FIFRA § 6(a)(2) by failing to timely submit Dr. Parry's report and his recommendations for further testing to the EPA. There is some evidence that Dr. Parry's report was relevant to the EPA's ability to conduct its continuing cost-benefit analysis on glyphosate. Martins, a Monsanto

toxicologist, testified during his deposition that Dr. Parry's "conclusions were well received" by the toxicologists, even though the stylistic "form of the report was not well received." (Docket Entry No. 69-3, at 437). Stephen Wratten, another Monsanto employee, stated in an email to Farmer and Heydens, that he was "somewhat disappointed in the Parry report, *not particularly from his conclusions* but just the way they're presented. The style and rather casual lack of completeness and preciseness would make it hard to circulate this around to anyone as supporting information." (*Id.*, at 270 (emphasis added)). Emails exchanged among Monsanto's toxicologists also show that the toxicologists were still debating how best to "rebut[]" Dr. Parry's report two years later after he originally submitted it. (*Id.*, at 272). This evidence plausibly suggests that while Dr. Parry's report had flaws, the flaws were primarily related to the form and presentation of his report, as opposed to the report's methodology, substance, and conclusions. The evidence also suggests that Monsanto's experts were concerned enough about the Parry report that they debated, for at least two years, about how to deal with it. A jury could reasonably conclude that Dr. Parry's conclusion—that glyphosate could be genotoxic and that further testing was needed—was, at minimum, relevant to whether Roundup products were misbranded.

The expert report of Dr. Charles M. Benbrook, which the Chapmans attached to their response to Monsanto's first motion for summary judgment before the MDL court, is further suggestive of the relevance of Dr. Parry's report. Dr. Benbrook wrote that

> [t]he new scientific information in the Parry [report] . . . was directly relevant to the EPA's evaluation of glyphosate and Roundup risks. The core findings and conclusions in these important reports . . . were profoundly inconsistent with the information EPA was currently relying on in estimating Roundup applicator exposure levels and associated risks. Monsanto was fully aware that the information in the Parry [report] . . . would substantially raise EPA concerns over the genotoxicity of Roundup and applicator exposure levels.

(Docket Entry No. 66-2, at 50). Dr. Benbrook then

> conclude[d] that Monsanto's failure to test formulated Roundup herbicides for genotoxicity, as recommended by Dr. Parry, is a primary reason why the EPA and other regulatory authorities have failed for decades to recognize the potential for glyphosate-based herbicides to increase the risk of cancer, including risk of NHL, via genotoxic mechanisms of action. In my opinion, Dr. Parry's reports contained the type of information that pesticide registrants are required to submit to the EPA under FIFRA Section 6(a)(2).

(*Id.*, at 98).

Monsanto argues, however, that evidence regarding its failure to submit the Parry report cannot be reviewed by the court or a jury. That is because, Monsanto argues, Section 82.008(c)(2)—which allows a plaintiff to rebut the presumption against liability by establishing that Monsanto "withheld from or misrepresented to the government or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury"—is preempted by federal law.

Monsanto relies on *Buckman Co. v. Pltf's Legal Comm.*, 531 U.S. 341 (2000), *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012), and *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002), for its preemption argument. In *Buckman*, the plaintiffs "claim[ed] injuries resulting from the use of orthopedic bone screws in the pedicles of their spines." 531 U.S. at 343. The plaintiffs alleged that their injuries occurred because the screw manufacturer, AcroMed Corporation, "made fraudulent representations to the Food and Drug Administration . . . in the course of obtaining approval to market the screws." *Id.* The Supreme Court held that the plaintiffs' state-law fraud claim was preempted by the Medical Device Act. *Id.* The court reasoned that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" and the FDA had authority to "punish and deter fraud against the [FDA]," without the additional and competing need for state-law tort claims. *Id.* at 348.

In *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012), the Fifth Circuit applied the Supreme Court's reasoning in *Buckman* to § 82.007(b)(1) of the Texas Civil Practice and Remedies Code, a similar statute to the one at issue in this case. Under § 82.007(a)(1), "a drug manufacturer enjoys a rebuttable presumption that it is not liable for failure to warn if the FDA has approved 'the warnings or information' accompanying the product alleged to have harmed the plaintiff." Tex. Civ. Prac. & Rem. Code § 82.007(a)(1)." A plaintiff can rebut that presumption "by establishing that . . . the defendant . . . withheld from or mispresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." *Id.* § 82.007(b)(1).

The Fifth Circuit held that § 82.007(b)(1) was preempted by federal law because the exception was "premised principally . . . on a drug maker's failure to comply with federal disclosure requirements." 672 F.3d at 379. The court understood § 82.007(b)(1) to require a plaintiff to prove "fraud on the FDA," *id.* at 376–77 ("[The plaintiffs must show fraud-on-the-FDA for their claims to survive . . . ."), even though the text of § 82.007(b)(1), like § 82.008(c)(2), does not require a plaintiff to establish all elements of a traditional fraud claim, including knowledge of falsity and intent.[5] The Fifth Circuit noted the Texas statute requires a plaintiff to "establish a violation of FDA's required disclosures," and "[i]n so doing, the plaintiff necessarily re-treads the FDA's administrative ground both to conduct discovery and to persuade a jury." *Id.* at 380. The court noted that federal law already "imposes penalties for omissions and misrepresentations" to the FDA, and "[a]s a result, disclosures to the FDA are 'uniquely federal' and thus beyond the states' traditional police power." *Id.* at 378–79. And the court further remarked that by allowing

[5] *Cf.* Avram Blair & G. Erick Rosemond, *Texas Pharmaceutical Failure-to-Warn Claims: Alive and Well*, 69 Tex. Bus. J. 728, 731 (2006) ("Critically, § 82.007's plain text does *not* require that a plaintiff show that a defendant committed fraud on *anybody*, let alone the FDA. And it imposes no requirement that the FDA itself determine it has been defrauded.").

a plaintiff to make a fraud-on-the-FDA argument under § 82.007(b)(1), the FDA would "in turn lose[] control over its ability, based on scientific expertise, to prescribe—and intelligently limit—the scope of disclosures necessary for its work," and "the statutory requirement of proving fraud-on-the-FDA [could] directly invade the agency's processes when close questions of 'withholding' or 'misrepresentation' arise." *Id.* at 380. "These dangers are inherent in *Buckman*'s concern to preserve the agency's discretion to police the conduct of regulated entities." *Id.*

Finally, in *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002), the Ninth Circuit concluded that federal law preempts fraud-on-the-EPA claims, in the same way it preempts fraud-on-the FDA claims. The court noted that:

> [T]he EPA has elaborate internal hearing and appellate review procedures to determine whether a registrant has violated any provision of FIFRA, including violations of FIFRA's statutory prohibition against the knowing submission of false information to the EPA. If a violation of FIFRA or its implementing regulations is found to have occurred, the EPA may impose substantial civil and criminal penalties. Furthermore, the United States Attorney is statutorily authorized to enforce such penalties on behalf of the EPA, and to otherwise prosecute any violation of FIFRA or its implementing regulations.

275 F.3d at 1206 (internal citations omitted).

"As was the case in *Buckman*," the Ninth Circuit stated, the "statutory scheme amply empowers the [EPA] to punish and deter fraud against the [EPA], and . . . this authority is used by the [EPA] to achieve a somewhat delicate balance of statutory objectives." *Id.* (quoting *Buckman*, 531 U.S. at 348). In holding that fraud-on-the-EPA claims are preempted by FIFRA, the court wrote:

> [W]e are troubled that an applicant's disclosures under FIFRA, although not challenged by the EPA (the very agency empowered by Congress to enforce FIFRA), may be judged illegal under state law. Such an approach would force FIFRA applicants to ensure that their disclosures to the EPA would satisfy not only the standards imposed by that agency under federal law, but also the potentially heterogeneous standards propounded by each of the 50 States. Such a holding would in turn motivate potential applicants under FIFRA to 'submit a deluge of

> information that the [EPA] neither wants nor needs, resulting in additional burdens on the [EPA's] evaluation of an application.' This outcome would needlessly drain the EPA of its limited resources, thereby detracting from its ability to efficiently enforce FIFRA.

Id. at 1207.

Based on the cases above, Monsanto is correct that the Chapmans' claim of fraud on the EPA under § 82.008(c)(2) is preempted by federal law. Section 82.008(c)(2) is almost identical to Section 82.007(b)(1), the provision at issue in *Lofton*. The sole difference between the two provisions is that § 82.007(b)(1) allows a plaintiff to rebut the presumption against liability by showing that the defendant withheld *required* information that was material and relevant. Section 82.008(c)(2) omits the word "required," and states only that a plaintiff must prove "the manufacturer, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the government or agency information that was material and relevant to the performance of the product." The *Lofton* court noted, however, that § 82.007(b)(1) was preempted, in part, because "what is 'material' and 'relevant' must be determined by FDA itself, not by state court juries." 672 F.3d at 379. The omission of the word "required" in § 82.008(c)(2) would not be material to the Fifth Circuit's preemption analysis.

The EPA, like the FDA, moreover, is empowered to determine what it "material and relevant" to registration under FIFRA, and the EPA can impose penalties for misrepresentations or omissions of information that would lead EPA to conclude that Roundup was misbranded. *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 951 (9th Cir. 2021), *cert. denied*, 142 S.Ct. 2834 (2022) ("Remedies for misbranding include civil and criminal penalties."); *see also id.* at 950–51 ("EPA can also institute cancellation proceedings . . . or take other enforcement action against the manufacturer of a registered pesticide if the agency determines the product is 'misbranded.'"). Because § 82.008(c)(2) requires the Chapmans to prove "fraud on the EPA," and because a finding

that the EPA's registration decision was invalid would interfere with the EPA's "substantial enforcement powers" under FIFRA, the court agrees with Monsanto that § 82.008(c)(2) is preempted.[6]

But Monsanto's preemption argument as to § 82.008(c)(2) is not relevant at this stage. Before deciding whether the Chapmans have shown a factual dispute material to determining whether it can rebut the presumption against liability under § 82.008(c)(2), it is first necessary to decide whether § 82.008(c)'s presumption applies at all. To be entitled to the presumption, it is Monsanto's burden, at trial and at summary judgment, to show that it complied with relevant EPA procedures and regulations for registration. *See* Tex. Civ. Prac. & Rem. § 82.008(c) ("[T]here is a rebuttable presumption . . . *if the product manufacturer* . . . *establishes* . . . that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval"). The *Lofton* Court stated that § 82.008(c)(2) was preempted because it required the plaintiff to establish fraud on the EPA. 672 F.3d at 380. Here, the burden is on Monsanto, not on the Chapmans, to establish compliance with FIFRA.

There are genuine factual disputes material to determining whether Monsanto did, in fact, comply with relevant federal regulations related to the registration of at least one pesticide product at issue in this case. Roundup Weed & Grass Killer Concentrate Plus was first conditionally registered by the EPA on October 31, 2001. (Docket Entry No. 72-3; Docket Entry No. 78). This was two years after Monsanto requested and had knowledge of the content of the Parry report.

[6] Section 82.008(c)(2) may not be preempted in all circumstances. If the EPA itself finds that Monsanto withheld material information, and institutes cancellation proceedings or other enforcement actions, the Chapmans could rely on that evidence without undermining the jurisdiction and authority of the EPA. *See Garcia v. Wyeth-Ayest Laby's*, 385 F.3d 961, 966 (6th Cir. 2004); *Ledbetter v. Merck & Co., Inc.*, No. 2005-59499, 2007 WL 1181991, at *10 (157th Dist. Ct., Harris Cnty., Tex. Apr. 19, 2007) (noting that § 82.007(b)(1) is "preempted [only] to the extent that someone other than the FDA is being asked to make the determination" that the defendant withheld material and relevant information).

Under § 6(a)(2), the Chapmans argue that Monsanto had a self-reporting duty to submit the Parry report to EPA as part of its continuing registration obligation for glyphosate, the active ingredient in Roundup Weed & Grass Killer Concentrate Plus. Because Monsanto did not submit the report, despite its obligation to do so, the EPA did not have the report when it considered the conditional registration of Roundup Weed & Grass Killer Concentrate Plus, in 2001. The EPA's conditional registration of pesticide products is premised on the EPA's registration of the pesticide product's component ingredients and Monsanto's duty to ensure that the glyphosate registration was accurate, up-to-date, and complaint with § 6(a)(2). Monsanto has not pointed to record evidence showing that it was either not required to submit the 1999 Parry report to the EPA as part of its § 6(a)(2) reporting duty for its glyphosate registration or when seeking conditional registration of Roundup Weed & Grass Killer Concentrate Plus, or that it did, in fact, produce the Parry report.[7]

Because there are factual disputes material to deciding whether Monsanto has established that it "complied with all of the government's or agency's procedures and requirement with respect to pre-market licensing or approval" of Roundup Weed & Grass Killer Concentrate Plus, Monsanto is not entitled to summary judgment on the application of the presumption against liability under § 82.008(c)(1).

ii. Rebutting the Presumption

A plaintiff can rebut the presumption against liability—if the presumption applies—by "establishing" that "(1) the standards or procedures used in the particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage; or (2) the manufacturer, before or after pre-market approval or licensing of the product,

[7] On this latter point, the evidence appears conclusive that Monsanto did not submit the Parry report. (*See* Docket Entry No. 66-3, at 437 (Q: "I assume by the same token that Monsanto never shared the Parry report with any regulatory agencies, correct?" A: "That's correct, yeah.")).

withheld from or misrepresented to the government or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury." Tex. Civ. Prac. & Rem. § 82.008(c)(1), (c)(2). As discussed, federal law preempts plaintiffs from rebutting the presumption of liability by proving that a defendant withheld from or misrepresented material and relevant information. This means that if the presumption against liability applies, the Chapmans can rebut the presumption only by showing that "the standards or procedures used in a particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage." Tex. Civ. Prac. & Rem. Code § 82.008(c)(1).[8] The Chapmans argue that "there is evidence showing that EPA's approval process has been inadequate to protect the public from unreasonable risk of injury," citing "[t]he Ninth Circuit's June 17, 2022, published Order in *Nat. Res. Def. Council v. U.S. Envtl. Prot. Agency*, No. 20-70787 (9th Cir. Jun. 17, 2022)," as "the most recent evidence." (*Id.*).

The Ninth Circuit opinion is not summary judgment record evidence in this case. But the opinion is relevant and suggestive of the potential inadequacy of the EPA's testing requirements for the registration of Roundup products. In *Nat. Res. Def. Council v. Envtl. Prot. Agency,* the National Resources Defense Council argued that the EPA "shirked its duties under the Endangered Species Act" when it determined in a 2020 Interim Registration Review Decision that glyphosate posed "no risks to human health." *NRDC*, 38 F.4th at 40–45. Congress requires "EPA to 'periodically review[]' pesticide registrations every fifteen years." *Id.* at 40 (quoting 7 U.S.C. § 136a(g)(1)(A)). "EPA has promulgated regulations delineating an elaborate process for

[8] This exception is unusual. This lawsuit is about whether Roundup-branded products more than likely caused Chapman's non-Hodgkin's lymphoma, and whether Monsanto should have warned about risks of cancer allegedly caused by Roundup usage, particularly over a long period. The adequacy of the EPA's registration process is not otherwise material or relevant to, and the EPA is not a party to this litigation. Monsanto did not raise or argue that § 82.008(c)(1) is preempted by federal law.

registration review," and "[t]he regulations . . . permit, but do not require, EPA to issue an 'interim registration review decision' prior to the registration review decision." *Id.* (quoting 40 C.F.R. § 155.56). The EPA issued an interim registration review decision in 2020, and the interim registration decision was the subject of the Ninth Circuit appeal.

In 2015, during the registration review process, the "EPA's pesticide unit made a preliminary determination that glyphosate was not likely to be carcinogenic and shared that determination with the agency's Office of Research and Development." *Id.* at 41. The Office of Research and Development noted several flaws with EPA's determination, and "[a]fter stating its methodological concerns, . . . expressed disagreement with the pesticide unit's determination that glyphosate was 'not likely to be carcinogenic.'" *Id.* at 42. The Office of Research and Development's "criticisms did not change EPA's overall 'not likely' determination." *Id.*

EPA then requested further feedback from an EPA-commissioned Scientific Advisory Panel. The Panel expressed similar concerns to the Office of Research and Development and noted that "the EPA evaluation [did] not appear to follow Cancer Guidelines" that were "intended to guide EPA in classifying chemicals according to their carcinogenic potential." *Id.* Again, EPA did not respond to the Office of Research and Development's concerns. "One year after receiving the [Panel's] feedback, EPA released a draft human-health risk assessment for glyphosate and an updated and final paper about glyphosate's carcinogenic potential," which still "concluded that glyphosate poses no serious human-health risks," and stated that "glyphosate should be classified as 'not likely to be carcinogenic to humans.'" *Id.* In January 2020, EPA released its Interim Registration Review Decision, which "announced that the earlier draft human-health and ecological risk assessments were now final—with no changes from those drafts." *Id.* at 43.

The National Resources Defense Council challenged EPA's conclusions on the impact of glyphosate on human health, among other EPA findings. *Id.* at 44. The Ninth Circuit "review[ed] EPA's Interim Decision for 'substantial evidence when considered on the record as a whole,'" and concluded that EPA's conclusion that glyphosate was not likely carcinogenic to humans was not supported by substantial evidence. The court noted that the Interim Decision "contravened the Cancer Guidelines it purported to follow" and reached irreconcilable conclusions. *Id.* at 45. The court stated that EPA improperly "discounted epidemiological studies" showing a "relationship between glyphosate and NHL." *Id.* at 46. The court noted that EPA inconsistently stated, on the one hand, that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available evidence," while on the other hand concluding that glyphosate was "not likely" to cause cancer. The court concluded that these two findings were irreconcilable, because EPA could not "reasonably treat its inability to reach a conclusion about NHL risk as consistent with a conclusion that glyphosate is 'not likely' to cause cancer within the meaning of the Cancer Guidelines." *Id.* at 46–47. The court vacated the "human-health portion" of the Interim Decision and remanded to the agency, noting that "further proceedings, including a new public-comment process, will be needed on remand." *Id.* at 52.

Two findings in the Ninth Circuit's decision are relevant to this litigation. First, the court found that "EPA's choice of the 'not likely' [carcinogenic] descriptor conflict[ed] with a determination EPA made earlier in [a] Cancer Paper," in which the EPA stated that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available evidence." *Id.* at 46. The court noted that

> the Cancer Paper discussed human epidemiological studies showing what could be considered suggestive evidence that glyphosate exposure causes [non-Hodgkins lymphoma] . . . [and] stated that "reported effect estimates across case-control studies and the associated meta-analyses [were] greater

> than 1," meaning that most studies EPA examined indicated that human exposure to glyphosate is associated with an at least somewhat increased risk of developing NHL. The Cancer Paper also acknowledged that some epidemiological studies provide evidence of an exposure-response relationship between glyphosate and NHL. One study, for instance, indicated that there was an increased risk of NHL for those with more than ten years of glyphosate exposure. In addition, that same study as well as another indicated that those who are exposed to relatively more glyphosate in a year face a higher risk of NHL. But EPA discounted epidemiological studies showing increased NHL risk by concluding that "chance and/or bias" could be "an explanation for observed associations in the database."

Id.

Second, the court noted that the EPA supported its selection of the "not likely" descriptor by stating that the "concerning results only occurred at high doses," and "mention[ed] that positive results in genotoxicity studies occurred only at 'high doses.'" *Id.* at 49. "Importantly, for both the rodent studies and genotoxicity studies," the Ninth Circuit stated, "[t]hese high doses [were] not considered relevant to human health risk assessment based on the currently registered use pattern for glyphosate" because "[m]aximum potential glyphosate exposure [had] been estimated at . . . 7 mg/kg/day . . . which [is] well-below the doses necessary to elicit the effects seen in these animal carcinogenicity and genotoxicity studies." *Id.*

The Ninth Circuit opinion highlights the fact that the EPA has not required or regarded as important genotoxicity studies involving high-dosages of glyphosate. The Chapmans have raised, throughout this litigation, other types of tests that the EPA has not required Monsanto or other glyphosate-product manufacturers to conduct as part of the registration of glyphosate and other Roundup-branded products. For example, the EPA requires carcinogenicity testing on the individual ingredients in Roundup, but not for the actual composite formulation. *See* EPA, *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment*, at 8 (Apr. 23, 2018), https://www.epa.gov/sites/default/files/2019-04/documents/hed-rtc-signed.pdf ("[T]hough

the EPA evaluates the [pesticide] product components, long term testing of individual products is not required."). Monsanto has admitted in interrogatories that it: "has never conducted an epidemiological study to study the association between glyphosate-containing formulations and non-Hodgkin's lymphoma"; "has not conducted a long-term animal carcinogenicity study on glyphosate since 1991"; and "has never conducted a 12-month or longer term animal carcinogenicity study on any surfactants used in glyphosate-based products." (Docket Entry No. 66-3, at 33). A Monsanto toxicologist has stated that Monsanto could not conclusively "say that Roundup does not cause cancer [because Monsanto had] not done carcinogenicity studies with Roundup." (*Id.*, at 276). The EPA has not required Monsanto to conduct these tests.

The Ninth Circuit opinion also supports the Chapmans' argument that the lack of any EPA requirement for high-dosage testing or long-term carcinogenicity testing of the formulated products has failed to protect the public from "unreasonable risks of injury," because at least one study has indicated that there is an increased risk of non-Hodgkin's lymphoma for those, like Chapman, with more than ten years of glyphosate exposure. Dr. Benbrook, the plaintiffs' expert on summary judgment before the MDL court, has similarly noted that Monsanto's failure to conduct "a long-term oncogenicity study utilizing formulated GBHs," and "[t]he absence of a single, well-designed chronic feeding oncogenicity study in mice or rats exposed to ***formulated glyphosate-based herbicides***, rather than pure glyphosate technical, is the most important single gap in the existing scientific appraisal of the human-health risks stemming from use of, and exposure to Roundup and other glyphosate-based herbicides." (Docket Entry No. 66-2, at 88 (emphasis in original)).

These statements and evidence support an inference that the EPA has not required or considered relevant long-term, high-dose carcinogenicity studies, particularly involving the

formulated Roundup products. *Cf. NRDC*, 38 F.4th at 50. The tens-of-thousands of defendants in the Roundup MDL and lawsuits around the country claiming that prolonged, long-term usage of Roundup-branded products caused their non-Hodgkin's lymphoma at least supports an inference that the EPA's current testing regime for licensing and approval of Roundup-branded products is inadequate to protect the public from unreasonable harm. Of course, at trial, the Chapmans have the burden of proving a causal link between Roundup usage and non-Hodgkin's lymphoma.

Because there are factual disputes material to determining whether the presumption against liability applies, the court need not decide at this stage of the case whether the Chapmans have presented sufficient evidence to rebut it by showing that the EPA's decision-making process in registering and reregistering Roundup-branded products was inadequate because the agency failed to require Monsanto to conduct and submit studies of the carcinogenicity risks of long-term exposure to Roundup products, including those at issue in this case. Relevant evidence on this issue at trial may include evidence as to the types of studies the EPA requires registrants to submit pre- and post-registration of pesticides and pesticide products, and whether specific long-term genotoxicity or carcinogenicity studies are necessary to protect the public from "unreasonable risk" of harm. The record shows that there are expert witnesses, some vetted by the MDL court, who are prepared to testify on these issues, such as Dr. Benbrook. There is sufficient evidence in the current record to create a triable issue as to whether the EPA's procedures were so inadequate as to rebut the presumption of nonliability created by the agency's approval. If, at trial, Monsanto believes that it has shown that the presumption applies under § 82.008(c) and has not been rebutted under § 82.008(c)(1), Monsanto can move for judgment as a matter of law. The evidence at trial will provide a much more secure footing for the court to rule on these issues of first impression.

IV. Conclusion

Monsanto's motion for summary judgment, Docket Entry No. 61, is denied. The arguments raised may be reurged at trial, on the basis of the fuller record the trial will provide. The court will hold a status conference on **September 26, 2022, at 10:00 A.M.**, by Zoom.

SIGNED on August 31, 2022, at Houston, Texas.

Lee H. Rosenthal
Chief United States District Judge