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COMMONWEALTH OF MASSACHUSETTS

ESSEX, ss.

SUPERIOR COURT
CIVIL ACTION
NO. 2177CV00462

PHYLLIS CARDILLO

vs.

MONSANTO COMPANY & other[1]

MEMORANDUM OF DECISION AND ORDER ON DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

This action arises out of allegations by the plaintiff, Phyllis Cardillo ("Cardillo"), that she developed non-Hodgkin's lymphoma, a form of cancer, as a result of her approximately twenty-eight-year exposure to Roundup®[2] products ("Roundup") manufactured by Monsanto Company ("Monsanto")[3] and sold at retail locations across the Commonwealth by Rocky's Hardware, Inc. ("Rocky's").[4] More specifically, Cardillo alleges that glyphosate, the most commonly used herbicide in the world, and an active ingredient in Roundup, is likely carcinogenic to humans and causes various forms of cancer. In January 2021, Cardillo filed a five-count complaint (the "Original Complaint") against the defendants, Monsanto and Rocky's. It alleged breach of warranty claims against Monsanto and Rocky's (Count I – design defect; Count II – failure to warn), and negligence, negligent misrepresentation and fraud, and unfair and deceptive trade practices in violation of G. L. c. 93A against Monsanto only (Count III; Count IV; Count V). Since filing the Original Complaint, Cardillo has amended it twice. Neither amendment has

[1] Rocky's Hardware Trust and Rocky's Hardware, Inc.

[2] Roundup® is herbicide used to kill weeds, whose active ingredient is glyphosate.

[3] Monsanto is an agricultural biotechnology corporation based in St. Louis, Missouri.

[4] Rocky's is a Massachusetts Corporation and surviving entity of Rocky's Hardware Business Trust.

resulted in any substantive changes to the Original Complaint, nor have the causes of action changed.

This matter is currently before the court on Monsanto's and Rocky's motions for summary judgment. While Monsanto's and Rocky's arguments in support of their motions differ in some respects, at least one issue raised by both is identical, and critical to the court's determination of their respective motions. A such, the court has decided to address all the issues raised by Monsanto's and Rocky's motions in the body of this single decision. After hearing, and for the reasons cited below, Monsanto's Motions for Summary Judgment are **ALLOWED** in part and **DENIED** in part, and Rocky's Motion for Summary Judgment is **ALLOWED** in part and **DENIED** in part.

BACKGROUND

The undisputed material facts viewed in the light most favorable to Cardillo, as the non-moving party, are taken from the Statement of Facts in Support of Defendant Rocky's Hardware, Inc.'s Motion for Summary Judgment (Paper No. 30.4), the Statement of Facts in Support of Monsanto's Motion for Summary Judgment on Preemption Grounds (Paper No. 31.4), and the Statement of Facts in Support of Monsanto's Motion for Summary Judgment on Plaintiff's Claims for Chapter 93A and Design Defect (Paper No. 32.4), as well as exhibits referenced therein. Some facts not specifically referenced here are reserved for discussion below.

Cardillo alleges that she was exposed to Roundup at her residence from approximately 1983 through 2019. In May of 2019, she was diagnosed with follicular lymphoma. She attributes the cause of her lymphoma diagnosis to the use of Roundup, which she purchased from Rocky's

and used approximately twice per year.[5] Her claim that Roundup caused her lymphoma is based on the opinion of her two retained experts who opine that her lymphoma was caused by her total exposure to Roundup but who have not performed a sperate causation analysis specific to Cardillo's purchases of Roundup from different locations.

Glyphosate is a non-selective, phosphonomethyl amino herbicide registered to control weeds. It is the active ingredient in Roundup, a weedkiller manufactured, marketed, and sold by Monsanto. As such, it is regulated by the United States Environmental Protection Agency ("EPA") under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). FIFRA requires that all manufacturers of pesticides, which are defined to include herbicides, register their product with the EPA before it can be sold. See note 9, *infra*. Registered pesticides are required to go through the registration process every fifteen years after approval and first sale. The EPA may not register a pesticide that causes "unreasonable adverse effects on the environment." This unreasonable adverse effect on the environment includes unreasonable risks to humans. A formulation change, such as removing or substituting an active ingredient, may only be accomplished through submission of an application for amended registration to the EPA.

The FIFRA registration process also requires the EPA to label the product. The labeling may not be false or misleading and so long as there is no cancellation process in effect, a pesticide's registration is prima facia evidence that the pesticide, its labeling, and its packaging comply with FIFRA's registration provisions. The EPA's approval of a label compels manufacturers to label and manufacture their products in a particular fashion, compels distributors and retailers to comply with the label's terms, including by restricting how and for

[5] Cardillo testified at her deposition that she also purchased Roundup from Lowes, and twice a year from Home Depot.

what uses the product can be sold, and compels the users to apply the pesticide only in the manners permitted by the terms of the pesticide's label. A violation of the label can result in criminal and civil penalties. Roundup has been subject to these regulations for decades, and Monsanto has received affirmative acceptance of the Roundup labels it has submitted to the EPA.

Glyphosate was initially registered with the EPA in 1974. It has continued to be registered over the years, in accordance with FIFRA and EPA regulations.

In 1991, the EPA, after conducting a registration review, concluded that "all registered uses of glyphosate are eligible for registration," and classified glyphosate as a chemical for which there exists "evidence of non-carcinogenicity for humans." In 2016, the EPA published an "issue paper" wherein it concluded that "[t]he strongest support is for [glyphosate] 'not likely to be carcinogenic to humans' at doses relevant to human health risk assessment." Such a classification is the lowest risk classification level with respect to cancer. Thereafter, in 2017, the EPA sought review of the carcinogenicity of glyphosate by an independent team of outside scientists, called the Scientific Advisory Panel. It subsequently published another "issue paper" wherein it again concluded that "[t]he strongest support is for [glyphosate] 'not likely to be carcinogenic to humans'."

In 2019, the EPA issued its Proposed Interim Registration Review Decision ("PID") on glyphosate, in which it affirmed that glyphosate is "'not likely to be carcinogenic to humans'" and that "[t]he EPA did not identify any human health risks from exposure to any use of glyphosate."[6]

[6] EPA's conclusion reflected in the PID that glyphosate is "not likely to be carcinogenic to humans" has been withdrawn by the EPA following a decision of the Ninth Circuit Court of Appeals in 2022. See *National Res. Def.*

The PID also addressed labeling. On the issue of carcinogenicity, the EPA required no modifications to the labeling of glyphosates and confirmed that no cancer warning is needed or appropriate for these glyphosate-containing products. In response to Proposition 65, a California law which required all businesses to inform Californians about significant exposures to chemicals that, under the terms of Proposition 65, are believed to cause cancer, the EPA sent a letter to all registrants of glyphosate on August 7, 2019, stating that the EPA considered the Proposition 65 warning language based on the chemical glyphosate to be "a false and misleading statement." As such, any label containing the Proposition 65 warning would make the product misbranded in violation of FIFRA. The letter ordered such a warning removed from all glyphosate-containing products and in essence prohibited the use of such a warning. In an April 2022 letter responding to California's March 2022 proposal to revise the warning, the EPA reaffirmed that the EPA "continues to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate" – namely, that glyphosate is unlikely to cause cancer.

All of this is not to suggest that the opinions of the EPA relative to the carcinogenicity of glyphosate are universally held. To the contrary, other health/environmental organizations have concluded differently. For example, in 2015, the International Agency for Research on Cancer ("IARC") concluded that glyphosate was "probably carcinogenic to humans." While the EPA has continued to stand firm on its conclusions in its 2019 letter, the EPA's 2022 letter also explained that the EPA could approve a label statement stating that IARC has "classified glyphosate as probably carcinogenic to humans" while also acknowledging that both the EPA

Council v. *United States Envtl. Prot. Agency*, 38 F.4th 34, 45-52 (9th Cir. 2022). This withdrawal of course occurred approximately two years after Cardillo's last know exposure to Roundup in 2019.

and other authorities have "determined that glyphosate is not likely to be carcinogenic to humans . . . ."

In 2020, the EPA published its glyphosate interim review decision and concluded therein that "there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." That portion of the interim decision has since been vacated by the Court of Appeals for the Ninth Circuit. *National Res. Def. Council* v. *United States Envtl. Prot. Agency*, 38 F.4th 34, 45 (9th Cir. 2022).

For approximately twenty-five (25) years, the EPA has repeatedly approved Monsanto's labels for Roundup which do not contain a cancer warning. And since September 2022, the EPA has registered at least a dozen glyphosate products and approved over two dozen glyphosate product labels, all without cancer warnings. Relevant to this case, the EPA's Pesticide Registration Notice 98-10 ("Preapproval Regulation"), published in 1998, prohibits Monsanto from making a "change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use" without first obtaining the EPA's approval. Since 2022, however, the EPA, has recognized the safe harbor language proposed by California's Office of Environmental Health Hazard Assessment and has allowed a warning, at the request of pesticide registrants, that "[u]sing this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans."

DISCUSSION

I. Standard of Review

Summary judgment shall be granted where there is no genuine dispute of material fact and the moving party is entitled to judgment as a matter of law. Mass. R. Civ. P. 56(c); *Barrows* v. *Wareham Fire Dist.*, 82 Mass. App. Ct. 623, 625 (2012), citing *Cassesso* v. *Commissioner of Corr.*, 390 Mass. 419, 422 (1983). A party moving for summary judgment is entitled to summary judgment if it affirmatively presents a set of undisputed facts that entitle it to a judgment as a matter of law, or if the moving party demonstrates that the party opposing the motion has no reasonable expectation of proving an essential element of that party's case. *Kourouvacilis* v. *General Motors Corp.*, 410 Mass. 706, 716 (1991).

The moving party "need not prove that no factual disputes exist, only that there is no genuine dispute of material fact." *Norwood* v. *Adams-Russell Co.*, 401 Mass. 677, 683 (1988). However, facts are viewed in the light most favorable to the non-moving party and all reasonable inferences are drawn against the moving party. *Attorney Gen.* v. *Bailey*, 386 Mass. 367, 371 (1982). Ultimately, summary judgment for the defendant is not appropriate if "anywhere in the evidence, from whatever source derived, any combination of circumstances could be found from which a reasonable inference could be drawn in favor of the plaintiff [as the nonmoving party]." *Mullins* v. *Pine Manor Coll.*, 389 Mass. 47, 56 (1983) (citations omitted).

II. Federal Preemption

The supremacy clause in art. 6 of the United States Constitution requires the court to declare invalid any State statute or regulation that attempts to regulate a field that Congress has reserved exclusively for itself. *Chadwick* v. *Board of Registration in Dentistry*, 461 Mass. 77, 84 (2011); *Commonwealth* v. *College Pro Painters (U.S.) Ltd.*, 418 Mass. 726, 728 (1994). See

Postal Cmty. Credit Union v. *Commissioner of Banks*, 61 Mass. App. Ct. 563, 568 (2004) ("[T]he supremacy clause . . . does not tolerate a conflict between Federal and State law on a given subject . . . ."). "A congressional intent to preempt State law may be stated explicitly in statutory language, or implicitly within the structure and purpose of a statute." *Dunn* v. *Genzyme Corp.*, 486 Mass. 713, 718 (2021). Accord *Archambault* v. *Archambault*, 407 Mass. 559, 565 (1990) ("Discussion of the application of Federal preemption principles generally takes place within the two categories of 'express' or 'implied' preemption, in which it is determined whether Congress (1) by express statement has preempted State law, or (2) by the nature of the Federal law has implied that State law is preempted."). Preemption is generally "'not favored, and State laws should be upheld unless a conflict with Federal law is clear[.]'" *Lynn* v. *Murrell*, 489 Mass. 579, 584 n.5 (2022) (first alteration and ellipses in original) (citation omitted).

Here, both Rocky's and Monsanto argue that they are entitled to judgment on all of Cardillo's claims as a matter of law. Their reasons differ, depending on the claim asserted, but on the issue of federal preemption, their arguments align. Both argue that Cardillo's claims are expressly and impliedly preempted by federal law, specifically, FIFRA, 7 U.S.C. § 136 *et seq.* See *Sawash* v. *Suburban Welders Supply Co.*, 407 Mass. 311, 315 (1990) ("'The burden is on the party seeking to displace the State action to show preemption with hard evidence of conflict based on the record.'" (citation omitted)).

A. Federal Preemption/Express

1. Applicable Statute

"Where, as here, a Federal statute 'contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Marsh* v.

Massachusetts Coastal R.R. LLC, 492 Mass. 641, 650 (2023) (citation omitted). See *Chadwick*, 461 Mass. at 84 ("The 'ultimate touchstone' of preemption is congressional intent, which courts discern through 'the explicit statutory language and the structure and purpose of the statute.'" (citations omitted)). As noted, the relevant statute is the Federal Insecticide, Fungicide, and Rodenticide Act.

Since 1972, FIFRA has regulated the use, sale, and labeling of pesticides. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991 (1984). See *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 437-440 (2005) (discussing history of FIFRA). It is a comprehensive regulatory scheme that provides for the review, cancellation, and suspension of pesticide registration, as well providing the EPA with enforcement authority. *Ruckelshaus*, 467 U.S. at 992. Under FIFRA, a manufacturer seeking to register a pesticide must submit a proposed label to the EPA, along with supporting data. 7 U.S.C. § 136a(c)(1)(C), (F); *Bates*, 544 U.S. at 438. The EPA will register a pesticide if it determines that the pesticide is effective, 7 U.S.C. § 136a(c)(5)(A); *Bates*, 544 U.S. at 438, and will not cause unreasonable adverse effects on humans and the environment. 7 U.S.C. § 136a(c)(5)(C), (D); *Bates*, 544 U.S. at 438. Once a label is approved, the pesticide may not be distributed or sold with a modified label until the EPA approves an amended registration. See 40 C.F.R. § 152.44(a).

Relevant to the arguments raised in this case, a product's labeling must also comply with the statute's prohibition against misbranding. 7 U.S.C. § 136a(c)(5)(B); *Bates*, 544 U.S. at 438. A pesticide is misbranded if the label contains statements that are false or misleading, fails to provide adequate instructions for use, or omits necessary warnings or cautionary statements. See 7 U.S.C. § 136(q)(1)(A), (F); *Bates*, 544 U.S. at 438. It is unlawful to sell a registered pesticide that is misbranded, and manufacturers have an ongoing obligation to adhere to FIFRA's labeling

requirements and to report incidents of a pesticide's toxic effects that may not be adequately reflected in its labeling warnings. *Bates*, 544 U.S. at 438-439 (2005).

Section 136v(b) provides that a state "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." See *Ajemian* v. *Yahoo!, Inc.*, 478 Mass. 169, 179 (2017) ("In interpreting a Federal statute, [courts] presume that Congress did not intend to intrude upon traditional areas of State regulation or State common law unless it demonstrates a clear intent to do so."). Monsanto and Rocky's argue that this provision expressly preempts Cardillo's claims because, as the EPA has determined that no cancer warning is required, Cardillo's proposed warning is both in addition to and different from the requirements that the EPA imposes.

2. Claims Subject to Preemption

In *Hochberg* v. *Zoecon Corp.*, 421 Mass. 456 (1995), approximately a decade before the United States Supreme Court rendered its decision in *Bates*, the Massachusetts Supreme Judicial Court ("SJC") stated that it was "undisputed that § 136v(b) explicitly prohibits States from imposing labeling or packaging 'requirements' that differ from those imposed by FIFRA." *Id.* at 459. The prohibition, the SJC held, applied to both statutes and regulations promulgated by the Commonwealth as well as to liability imposed by State breach of warranty and negligence law, concluding "that Congress' intent in enacting § 136v(b) of FIFRA was to preclude States not only from mandating labeling and packaging requirements by means of statute or regulation, but also to preclude States from achieving a similar result through the establishment and application of pertinent tort law." *Id.* at 461. Section 136v(b), then, "preempts all State action pertaining to labeling requirements." *Id.*

Approximately ten years after the SJC's decision in *Hochberg*, the United States Supreme Court considered for the first time whether FIFRA preempts torts and other common-law claims. *Bates*, 544 U.S. at 441. While considering similar issues addressed in *Hochberg* and raised by the current motions in this case – namely, can a plaintiff's fraud and negligent failure to warn claims qualify as "requirements for labeling or packaging" – it also considered whether § 136v(b) preempts other common-law tort claims such as design defect and straight negligence claims. See *id.* Compare *Hochberg*, 421 Mass. at 461 (addressing only plaintiff's claim premised on theory of inadequate warning or labeling).

At issue in *Bates* for purposes of preemption were claims of "breach of express warranty, fraud, violation of the Texas [deceptive trade practices act], strict liability (including defective design and defective manufacture), . . . negligent testing. . . . [and] negligent failure to warn . . . ." *Bates*, 544 U.S. at 442 n.15. In its analysis, the Court considered the scope of the preemption, drawing a distinction the SJC had not addressed, that is, between common-law fraud and duty-to-warn claims, and tort claims unrelated to the imposition of a requirement for "labeling or packaging." *Id.* at 443-444. The Court held that a state rule will only be preempted if it is "a requirement '*for labeling or packaging*'; rules governing the design of a product, for example, are not pre-empted." *Id.* at 444 (emphasis in original). Similarly, "[a]n occurrence that merely motivates an optional decision does not qualify as a requirement." *Id.* at 443.

Therefore, "[r]ules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for 'labeling or packaging.' None of these common-law rules requires that manufacturers label or package their products in any particular way." *Id.* at

444. Thus, FIFRA does not expressly preempt Cardillo's design defect, negligence, and unfair and deceptive trade practices claims. See *id.*

Cardillo's negligent failure to warn and fraud claims, however, stand on a slightly different footing. Those claims are based on common-law rules that do qualify as "requirements for labeling or packaging" under FIFRA. *Bates*, 544 U.S. at 446; *Hochberg*, 421 Mass. at 461. As such, they are prohibited, but only if the state common-law requirements are "in addition to or different from" the labeling and packaging requirements under FIFRA. *Bates*, 544 U.S. at 447.

3. Preemption Analysis

FIFRA does not preclude State involvement in the regulation of pesticides, it only prohibits State involvement that is inconsistent with the statute. See 7 U.S.C. § 136v ("A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter. . . . [and] [s]uch State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter."). As stated in *Bates:*

> "States have ample authority to review pesticide labels to ensure that they comply with both federal and state labeling requirements. Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law. The imposition of state sanctions for violating state rules that merely duplicate federal requirements is equally consistent with the text of § 136v."

544 U.S. at 442 (footnote omitted). See *id.* at 450 ("[T]he statute authorizes a relatively decentralized scheme that preserves a broad role for state regulation. . . . A literal reading of § 136v(b) is consistent with the concurrent authority of the Federal and State Governments in this sphere."). "That Congress added the . . . ['in addition to or different from' language in § 136v(b)]

is evidence of its intent to draw a distinction between state labeling requirements that are preempted and those that are not[,]" *id.* at 449, and it also "seems unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability." *Id.* at 450.

Thus, the *Bates* Court adopted a "parallel requirement" reading of § 136v(b), in which it held that a State cause of action does not preclude a State from providing "traditional" remedies for violations of common-law duties when those duties "parallel federal requirements." See *id.* at 447-448, quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 496 (1996) (addressing preemption in context of Florida common-law remedies related to federal statute regulating medical devices). In other words, "although FIFRA does not provide a federal remedy to . . . [those] who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy." *Id.* at 448. In fact, "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA." *Id.* at 451.

The Court concluded that § 136v(b) "preempts competing state labeling standards . . . that would create significant inefficiencies for manufacturers. . . . [as well as] any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations. It does not, however, preempt any state rules that are fully consistent with federal requirements." *Id.* at 452. Thus, a state-law labeling requirement survives preemption if it is "in fact . . . [genuinely] equivalent to a requirement under FIFRA . . . ." *Id.* at 453, 454.

Under Massachusetts law, a manufacturer has a duty to warn purchasers of dangers involved in the use of its product of which the manufacturer knows or reasonably should know.

Mitchell v. *Sky Climber, Inc.*, 396 Mass. 629, 631 (1986). To determine whether this requirement is not in addition to or different from FIFRA's requirements, the court must compare it to the federal labeling requirement. See *Bates*, 544 U.S. at 445 ("The proper inquiry calls for an examination of the elements of the common-law duty at issue . . . ."). If Roundup's label violates both federal and state-law labeling requirements, it conforms to the parallel requirement and the state duty-to-warn claim is not preempted; if, on the other hand, Roundup's label violates Massachusetts's common-law duty-to-warn but does not violate FIFRA's labeling requirements, it is not parallel and is preempted. See *Bates*, 544 U.S. at 454.

While common-law duty-to-warn requirements vary slightly from state to state, for purposes of the issues raised in this case, they are essentially the same. For example, Pennsylvania's product liability law deems a product defective if it "was 'distributed without sufficient warnings to notify the ultimate user of the dangers inherent in the product.'" *Phillips* v. *A-Best Prods. Co.*, 542 Pa. 124, 131 (1995) (citation omitted). Similarly, Georgia law imposes a common-law duty on "suppliers of chattel" "to warn of foreseeable dangers arising from the reasonable use for which the product is intended and requires the exercise of reasonable care to inform [the product's users] of the dangerous condition or of the facts which make the product likely to become dangerous." *R & R Insulation Servs.* v. *Royal Indem. Co.*, 307 Ga. App. 419, 427 (2010) (citation omitted). And, in California, manufacturers generally have a duty to warn consumers about the hazards inherent in their products. See *Anderson* v. *Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1003 (1991). Therefore, considering whether FIFRA's labeling requirements expressly preempt Massachusetts's common-law duty-to-warn claims naturally requires this court to follow the same or similar analysis followed by courts throughout the country dealing with State common-law duty-to-warn claims alleged against Monsanto. A

review of those cases is helpful, but only marginally so, as courts across the country are split on the issue.

For example, in 2021 the Court of Appeals for the Ninth Circuit held that FIFRA did not expressly preempt a plaintiff's California failure-to-warn claim because the State's failure-to-warn requirement was parallel and consistent with FIFRA's misbranding provision which requires a pesticide's label to contain a warning or caution statement necessary to adequately protect health and the environment. See *Hardeman* v. *Monsanto Co.*, 997 F.3d 941, 955-958 (9th Cir. 2021). Recently, however, the Court of Appeals for the Third Circuit held differently, holding that FIFRA would preempt a Pennsylvania common-law duty to warn requirement that would mandate Monsanto modifying its Roundup label to provide a cancer warning because it would require specific statements pertaining to hazards associated with Roundup that require preapproval from the EPA. See *Schaffner* v. *Monsanto Corp.*, 113 F.3d 364, 385 (3rd Cir. 2024) (holding that "[b]ecause the EPA does not approve label contents added through modification by notification, that procedure cannot be used to add contents, such as the Cancer Warning, that 'must be approved by the [EPA]'").

Schaffner framed the difference between the two lines of cases in terms of the levels of generality at which FIFRA's labeling requirements are articulated:

> "When state tort law and a federal statute seem to impose equivalent requirements, but a federal regulation gives different content to that apparently equivalent requirement, should a court articulate the Federal Comparator at the broader statutory level of generality or the more specific regulatory level of generality? That question determines what Federal Comparator [the court] must employ when applying the parallel-requirements test in this case. Should [the court] ask whether the [relevant State's] Duty to Warn is equivalent to FIFRA's broad statutory requirement that labels contain all necessary warnings, or whether it is equivalent to the specific regulatory requirement that a pesticide's label must contain particular contents included on its Preapproved Label, including the precautionary statements?"

113 F.4th at 390. *Hardeman*, 997 F.3d at 955-956, for example, applied the "broad statutory requirement" and found no preemption, while *Schaffner*, 113 F.4th at 390, applied the specific regulatory requirement – the Preapproval Regulation, PR 98-10[7] – and found preemption. See *id.* at 385-389 (explaining application of Preapproval Regulation to analysis).

While neither case is binding on this court, this court finds *Schaffner*'s reasoning persuasive as it is consistent with *Bates*, which held "that a state-law duty is preempted if 'relevant EPA regulations that *give content to* FIFRA's misbranding standards[]' . . . would prohibit adding the warning that state law requires." *Schaffner*, 113 F.4th at 391 (emphasis added), quoting *Bates*, 544 U.S. at 453. See *id.* at 390-392 (explaining that "under both *Bates* and section 136v(b) itself federal requirements must be articulated at the more specific level when identifying the Federal Comparator in applying the parallel-requirements test"). "[T]he Preapproval Regulation . . . gives content to FIFRA's misbranding standards" in that it "requires pesticide labels to conform to the EPA's opinion as to whether specific labels would constitute misbranding," thereby giving content to "the broad requirement that such labels not be misbranded." *Id.* at 391, citing *Bates*, 544 U.S. at 453.

Here, while Cardillo claims in her factual allegations that Roundup caused her cancer, Count II of the Second Amended Complaint does not specify how a revised Roundup label would read, except to assert that Monsanto had a duty to warn that Roundup contains "dangerous characteristics" which include the active ingredient, "glyphosate," and that it "knew or should have known the unreasonable risks of harm associated with the use of and/or exposure to such

[7] The Preapproval Regulation is available at https://www.epa.gov/sites/default/files/2014-04/documents/pr98-10.pdf (last visited October 17, 2024). This court finds persuasive the conclusion in *Schaffner*, 113 F.4th at 386, that the Preapproval Regulation is a rule of law that must be obeyed, rendering it a "requirement" for purposes of 7 U.S.C. § 136v(b).

products." The allegation in Count II that Monsanto failed to warn of the "dangerous propensities of its products and the carcinogenic characteristics of glyphosate," lead this court to conclude that any modified Roundup label would at a minimum require a warning that glyphosate is the active ingredient in Roundup and that it is carcinogenic. Though Cardillo argues only that under Massachusetts's common-law duty to warn, Roundup has been misbranded because its label fails to contain a warning that does not adequately reflect glyphosate's toxic effects about which Monsanto knows or should know, see 7 U.S.C. § 136(q)(1)(A), (F); *Bates,* 544 U.S. at 438-439, the reality of Cardillo's claim would make any label that falls short of a "Cancer Warning," a violation of the State's common-law duty to warn.

Briefly, "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')," *Schaffner*, 113 F.4th at 371, and modifications to the Preapproval Label may be accomplished in three different ways. First, a registrant may file with the EPA "an application for amended registration" for "any modification in the composition, labeling, or packaging of a registered product . . . ." 40 C.F.R. § 152.44(a). Second, the "EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the [EPA], without requiring that the registrant obtain [EPA] approval." 40 C.F.R. § 152.46(a)(1). Third, the "EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished without notification to or approval by the [EPA]." 40 C.F.R. § 152.46(b).

The Preapproval Regulation "expand[ed] the changes to registration which may be made by notification and non-notification . . . ." Preapproval Regulation, at 1. Section II lists the types

of registration amendments that may be accomplished by notification. See Preapproval Regulation, § II(A)-(N), at 2-8. The final subsection is "a catchall provision encompassing minor label changes that do not fall under any earlier item[,]" *Schaffner*, 113 F.4th at 383, and provides that any other minor label changes not mentioned may be made by notification as long as they, inter alia, "involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use." Preapproval Regulation, § II(N)(3), at 8. As a matter of law, a warning that Roundup may be carcinogenic is a precautionary statement that Monsanto could not have added by notification. See *id.* See, e.g., *Schaffner*, 113 F.4th at 384 ("Because adding the Cancer Warning would involve "a change . . . in precautionary statements,' [the Preapproval Regulation] does not permit it to be added through modification by notification."). Section IV lists the types of registration amendments that may be accomplished without notification to the EPA, see Preapproval Regulation, § IV(A)-(J), at 11-14, which, again as a matter of law, do not include Cardillo's requested warning. Thus, Monsanto could only have sought an amendment to the Roundup label by filing "an application for amended registration" with the EPA pursuant to 40 C.F.R. § 152.44(a), which it did not do.[8]

Monsanto's omission of Cardillo's requested warning from the Roundup label allegedly violated the Massachusetts duty to warn, but this omission did "not breach the Preapproval

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[8] Here, too, this court agrees with *Schaffner*:

> "Monsanto has not claimed that it ever submitted an application for amended registration or sought EPA approval for a modified Roundup label that included the Cancer Warning [that the plaintiff sought in that case]. A plaintiff might conceivably argue that FIFRA required Monsanto to submit such an application and that a state-law claim for breach of the duty to warn could satisfy the parallel-requirements test because it is equivalent to that federal requirement. Because the [plaintiffs] advanced no such argument here, however, [the court] [did] not consider it, and . . . express[ed] no opinion as to whether it could succeed."

113 F.4th at 386 n.13. Cardillo also does not make that argument here.

Regulation – and thus the Federal Comparator – because Roundup's Preapproved Label omitted [Cardillo's requested warning]." *Schaffner*, 113 F.4th at 393. "As Monsanto's alleged violation of the [Massachusetts] Duty to Warn did not constitute a violation of the Federal Comparator, the two requirements are not equivalent, the parallel-requirements test is not satisfied," *id.*, and Cardillo's claims for failure to warn and fraud are preempted under 7 U.S.C. § 136v(b).

Monsanto and Rocky's motions for summary judgment on preemption are accordingly **ALLOWED** as to Counts II (breach of warranty – failure to warn) and IV (negligent misrepresentation and/or fraud) in full, and as to Counts III (negligence) and V (unfair and deceptive trade practices) only insofar as they allege a failure to warn.

B. Federal Preemption/Implied

As noted, in addition to being expressly preempted, state law may be impliedly preempted, which occurs either when "the Federal law so thoroughly occupies a legislative field such that it is reasonable to infer that Congress left no room for the State to supplement it (field preemption)," or "the State law actually conflicts with the Federal law (conflict preemption)." *Marsh*, 492 Mass. at 648. Appropriately, Monsanto does not raise field preemption, as the Supreme Court has held that "FIFRA [is] not 'a sufficiently comprehensive statute to justify an inference that Congress had occupied the field to the exclusion of the States.' . . . 'To the contrary, the statute leaves ample room for States and localities to supplement federal efforts even absent the express regulatory authorization of § 136v(a).'" *Bates*, 544 U.S. at 441-442 (citation omitted).

Instead, Monsanto argues that it is impossible for it to comply with both FIFRA requirements and contrary State-law requirements. See *Marsh*, 492 Mass. at 648 n.18 ("Conflict preemption occurs when 'it is impossible for a private party to comply with both [S]tate and

[F]ederal requirements, . . . or where [S]tate law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" (alterations and ellipses in original) (citations and internal quotation marks omitted)). As this court has already concluded that FIFRA expressly preempts Cardillo's duty-to-warn and fraud claims, it need not consider whether those claims are impliedly preempted as well. See *Gade* v. *National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (considering implied preemption "[a]bsent explicit preemptive language"); *Marsh*, 492 Mass. at 658-659 (noting that court may consider implied preemption after finding no express preemption); *Archambault*, 407 Mass. at 566 (considering implied preemption "in the absence of express preemption"). See also *Bates*, 544 U.S. at 459 (Thomas, J., concurring in part and dissenting in part) (noting Court's "reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"). Compare *Cipollone* v. *Liggett Grp., Inc.*, 505 U.S. 504, 532 (1992) (Blackmun, J., concurring in part and dissenting in part) ("[Courts] resort to principles of implied pre-emption – that is, inquiring whether Congress has occupied a particular field with the intent to supplant state law or whether state law actually conflicts with federal law . . . – only when Congress has been silent with respect to pre-emption."), with *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 288-289 (1995) ("The fact that an express definition of the pre-emptive reach of a statute 'implies – i.e., supports a reasonable inference – that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied pre-emption. . . . [and] [a]t best, *Cipollone* supports an inference that an express pre-emption clause forecloses implied pre-emption; it does not establish a rule.").

III. Design Defect

"For a product to be defective, it must be "made according to an unreasonably dangerous design and does not meet a consumer's reasonable expectation as to its safety.'" *Niedner* v.

Ortho-McNeil Pharm., Inc., 90 Mass. App. Ct. 306, 312 (2016) (citations and internal quotation marks omitted). Liability based on defective design may be predicated on a theory of breach of warranty or a theory of negligence. *Haglund* v. *Philip Morris, Inc.*, 446 Mass. 741, 747 & n.9 (2006). "In a negligence action, the conduct of the defendant takes center stage, and liability will be imposed where the defendant 'has failed to use reasonable care to eliminate foreseeable dangers which subject a user to an unreasonable risk of injury.'" *Id.* at 747 n.9 (citation omitted). "Unlike negligence liability, warranty liability 'focuses on whether the product was defective and unreasonably dangerous and not on the conduct of the user or the seller.'" *Colter* v. *Barber-Greene Co.*, 403 Mass. 50, 61-62 (1988) (citation omitted). "Because a breach of warranty does not require a defendant's misconduct, a defendant may be liable on a theory of breach of warranty of merchantability even though he or she properly designed, manufactured, and sold his or her product." *Id.* at 62 (footnote omitted).

Cardillo has predicated her claim that Roundup was defectively designed under both theories. In Count I (breach of warranty – design defect), Cardillo alleges that Monsanto designed Roundup in an unsafe, defective, and unreasonably dangerous manner because its active ingredient is the cancer-causing glyphosate, and that Rocky's is liable for being part of the chain of distribution of this allegedly defective product. In Count III (negligence), Cardillo alleges that Monsanto failed to design Roundup to ensure that it was safe, that Monsanto knew or should have known the carcinogenic properties of glyphosate, and that Monsanto knew or should have known that it was foreseeable that consumers, such as Cardillo, would suffer injuries, such as non-Hodgkin's lymphoma, from exposure to Roundup.

A. Feasible Alternative Design

Monsanto seeks summary judgment on Cardillo's design defect claims because Cardillo has not demonstrated that she will be able to prove at trial that a feasible alternative design was available that would have reduced or prevented her harm. Rocky's has joined Monsanto's motion on this basis.

"'[T]here is a case for the jury if the plaintiff can show an available design modification which would reduce the risk without undue cost or interference with the performance of the machinery.'" *Colter*, 403 Mass. at 57 (alteration in original) (citation omitted). "The plaintiff need only convince the jury that a safer alternative design was feasible, not that any manufacturer in the industry employed it or even contemplated it." *Haglund*, 446 Mass. at 748.

Cardillo has submitted a report from toxicologist Jenifer S. Heath, Ph.D. ("Dr. Heath"), who observed that glyphosate's "'dermal absorption rate . . . is influenced by surfactants and the amount of glyphosate in the concentrate formulation.' In other words, surfactants matter and Roundup products . . . have different (greater) toxicity-related properties than does the active ingredient (glyphosate) alone." Monsanto Exhibit 1, at 34. Dr. Heath opined that "[g]lyphosate is known to penetrate the skin and be distributed throughout the body (via plasma/circulation and diffusion) and stored in bone/bone marrow. In addition, bone is a well-perfused tissue. The surfactants in formulations like various roundup products increase dermal absorption of glyphosate." Monsanto Exhibit 1, at 82. From this opinion, a reasonable fact finder could infer that the elimination of "surfactants" in Roundup would reduce the risk of harm from exposure to glyphosate.

Monsanto and Rocky's motions for summary judgment on Cardillo's design defect claims are therefore **DENIED** as they have failed to demonstrate that Cardillo will be unable to prove an alternative feasible design at trial.

B. Causation

Cardillo has demonstrated that she will be able to prove at trial that Roundup is defective, unreasonably dangerous, and caused her non-Hodgkin's lymphoma. Rocky's moves for summary judgment on Count I on the basis that Cardillo will be unable to prove at trial that the Roundup that she purchased at Rocky's caused her non-Hodgkin's lymphoma. As noted, warranty liability focuses not on the seller's conduct but on whether the product was defective and unreasonably dangerous. *Colter*, 403 Mass. at 61-62 (1988). "[A]ll commercial sellers and distributors of products, including nonmanufacturing sellers and distributors such as wholesalers and retailers, are subject to liability for selling products that are defective. Liability attaches even when such nonmanufacturing sellers or distributors do not themselves render the products defective and regardless of whether they are in a position to prevent defects from occurring." Restatement (Third) of Torts: Products Liability § 1, cmt. e (1998).

Cardillo testified that in addition to Rocky's, she also purchased Roundup from Home Depot and Lowes, but that her memory was that she "tried to shop at Rocky's more . . . ." Rocky's Exhibit 1 (Cardillo's deposition), at 103. Where, as here, the fact finder is presented with multiple potentially competing causes, it does not have to make a but-for causation finding. *Doull* v. *Foster*, 487 Mass. 1, 18 (2021). Rather, the fact finder "should be instructed that when 'there are two or more competing causes . . . each of which is sufficient without the other to cause the harm and each of which is in operation at the time the plaintiff's harm occurs, the factual causation requirement is satisfied.'" *Id.* (citation omitted).

Rocky's motion for summary judgment on Count I is accordingly **DENIED** on this basis as well.

IV. G. L. c. 93A

In Count V, Cardillo alleges that Monsanto's manufacturing, selling, and distributing Roundup in a defective and unreasonably dangerous condition is a breach of the implied warranty of merchantability that constitutes unfair and deceptive acts and practices in violation of G. L. c. 93A, § 2. Monsanto argues that the "safe harbor" provision in G. L. c. 93A, § 3 ("section 3"), exempts it from liability under G. L. c. 93A.

Section 3 provides that "[n]othing in this chapter shall apply to transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States." "A defendant's burden in claiming the exemption is 'a difficult one to meet. To sustain it, a defendant must show more than the mere existence of a related or even overlapping regulatory scheme that covers the transaction. Rather, a defendant must show that such scheme *affirmatively permits* the practice which is alleged to be unfair or deceptive[.]" *Commonwealth* v. *Fremont Inv. & Loan*, 452 Mass. 733, 750 (2008) (emphasis added) (citations omitted). "Inferences cannot be the basis for satisfying the defendants' heavy burden under the statute." *Aspinall* v. *Philip Morris, Inc.*, 453 Mass. 431, 436 (2009).

Here, then, Monsanto must show that the EPA allows the manufacture, sale, and distribution of defectively designed products. See *id.* It does not. Rather, as discussed above, FIFRA is a comprehensive regulatory scheme that provides for the review, cancellation, and suspension of pesticide registration.[9] *Ruckelshaus*, 467 U.S. at 992. In registering a product, the

[9] "[N]o person in any State may distribute or sell to any person any pesticide that is not registered under" FIFRA. 7 U.S.C. § 136a(a). To register a pesticide, an applicant must file with the EPA a "statement" that includes, inter alia,

EPA does not approve of a product's design; thus, "[t]he EPA's approval of a product's FIFRA label does not constitute a finding or an endorsement that its design is safe." *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 837 (N.D. Ill. 2002). Accord 7 U.S.C. § 136a(f)(2) ("In no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions . . . .").

The court finds persuasive the Federal District Court of West Virginia's explanation of the EPA's lack of involvement in a product's design:

> "The registration of a pesticide by EPA is not a performance standard . . . . [The applicant] is not obligated to formulate [its product] according to some EPA-imposed composition. Rather, it is [the applicant's] burden to design its product,

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"the complete formula of the pesticide[,]" 7 U.S.C. § 136a(c)(1)(D), and "a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the [EPA] and that the [EPA] may consider in accordance with" certain provisions. 7 U.S.C. § 136a(c)(1)(F). See 7 U.S.C. § 136a(c)(2) ("The [EPA] shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time."). "The [EPA] shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide . . . or notify the applicant of the [EPA's] determination that it does not comply with the provisions of" FIFRA. 7 U.S.C. § 136a(c)(3)(A).

The EPA will register a pesticide if it determines that:

> "(A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

7 U.S.C. § 136a(c)(5). If those requirements are not satisfied, the EPA will notify the applicant that, "unless the applicant corrects the conditions and notifies the [EPA] thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the [EPA] may refuse to register the pesticide. Whenever the [EPA] refuses to register a pesticide, the [EPA] shall notify the applicant of the [EPA's] decision and of the [EPA's] reasons (including the factual basis) therefor." 7 U.S.C. § 136a(c)(6). "As a part of the registration of a pesticide the [EPA] shall classify it as being for general use or for restricted use [or both]." 7 U.S.C. § 136a(d)(1)(A). See 7 U.S.C. § 136a(d)(1)(B) (general use explained); 7 U.S.C. § 136a(d)(1)(C) (restricted use explained).

> obtain and submit the data and studies required by EPA, and develop the appropriate label to instruct proper use. EPA depends upon the applicant to perform the tests, assemble the studies, and provide the data upon which EPA relies in registering the product and approving the label. EPA does not independently test, study, or otherwise set particular composition standards for the pesticides. EPA's approval, including the general finding of no measurable adverse [e]ffects, does not dictate to [the applicant] a particular composition; it merely allows [the applicant] to market what [the applicant] has developed and requires it to conform the composition and label to that which [the applicant] has obtained approval."

Jeffers v. *Wal-Mart Stores, Inc.*, 171 F. Supp. 2d 617, 623-624 (S.D.W.V. 2001).[10]

Monsanto is therefore not entitled to section 3's safe harbor exemption, and its motion is **DENIED** on this basis.[11, 12]

CONCLUSION AND ORDER

For the reasons set forth above, Monsanto's and Rocky's motions for summary judgment are **ALLOWED** as to Counts II and IV in full, and as to Counts III and V only insofar as they allege a failure to warn, otherwise the motions are **DENIED**.

SO ORDERED.

Salim Rodriguez Tabit
Justice of the Superior Court

Date: October 21, 2024

[10] This court acknowledges that this discussion was in the context of whether FIFRA impliedly preempted the plaintiff's design defect claims.

[11] This argument fails procedurally as well because Monsanto's "reliance on G. L. c. 93A, § 3, properly should have been stated as an affirmative defense in its answer[,]" *Fremont Inv. & Loan*, 452 Mass. at 749, but it was not.

[12] Notwithstanding this court's conclusion that FIFRA preempts Cardillo's failure to warn claims, section 3 does exempt Monsanto from liability under G. L. c. 93A insofar as Count V concerns labeling as the EPA affirmatively permits a label *without* a warning that glyphosate is carcinogenic.