PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 22-3075

DAVID SCHAFFNER, JR.; THERESA SUE SCHAFFNER

v.

MONSANTO CORPORATION
Appellant

On Appeal from the United States District Court
for the Western District of Pennsylvania
(D.C. Civil No. 2:19-cv-01270)
Magistrate Judge: Honorable Cynthia R. Eddy

Argued October 19, 2023

Before: CHAGARES, Chief Judge, PHIPPS and CHUNG,
Circuit Judges

(Filed August 15, 2024)

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OPINION OF THE COURT

CHAGARES, Chief Judge.

This appeal presents the question of whether, once the Environmental Protection Agency ("EPA") registers and approves a pesticide label that omits a particular health

warning, a state-law duty to include that warning is preempted by a federal statute expressly preempting any state-law pesticide labeling requirement that differs from or adds to the requirements imposed under federal law. Plaintiffs David Schaffner, Jr. and Theresa Sue Schaffner allege that defendant Monsanto Company ("Monsanto")[1] violated Pennsylvania law by omitting a cancer warning from the label of its weed-killer, Roundup (the "Cancer Warning"). But the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq., the federal statute that regulates pesticides such as Roundup, mandates nationwide uniformity in pesticide labeling by prohibiting states from imposing labeling requirements that are in addition to or different from the requirements imposed under FIFRA itself. This provision, Monsanto argues, preempts the Pennsylvania duty to warn that it allegedly breached. Because regulations promulgated to implement FIFRA require the health warnings on a pesticide's label to conform to the proposed label approved by the EPA during the registration process (the "Preapproved Label"), and because during Roundup's registration process the EPA approved proposed labels omitting a cancer warning following an extensive review of scientific evidence concerning Roundup's possible carcinogenicity, we conclude that the alleged state-law duty to include the Cancer Warning on Roundup's label (the "Pa. Duty to Warn") imposes requirements that are different from those imposed under FIFRA, and that it is therefore preempted by FIFRA. The

[1] Although Monsanto was sued under the name "Monsanto Corporation," it is in fact named "Monsanto Company." See, e.g., Bayer, Bayer Closes Monsanto Acquisition (June 7, 2018), https://www.bayer.com/media/en-us/bayer-closes-monsanto-acquisition [https://perma.cc/XVX7-R69B].

judgment in the Schaffners' favor that was stipulated to by the parties and entered by the District Court reflected a prior ruling, issued during consolidated multi-district pretrial proceedings held in an out-of-circuit judicial district, that FIFRA did not preempt state-law tort duties to include the Cancer Warning on the Roundup label. We will therefore reverse the judgment of the District Court.

We first provide background in Part I, addressing pesticide regulation under FIFRA, the dispute over Roundup's carcinogenicity, and the Schaffners' claims in this case, then we discuss our jurisdiction and the standard of review in Part II. In Part III, we consider and reject the Schaffners' arguments that certain doctrines require our decision in this case to conform to the prior rejection of Monsanto's preemption theory by other courts in other litigation. Instead, we conclude that we must independently interpret FIFRA's express preemption scheme ourselves. We present our interpretation in Part IV, applying it to conclude that the Schaffners' claims are expressly preempted by FIFRA. An EPA regulation promulgated pursuant to FIFRA (the "Preapproval Regulation") prohibits modifying the health warnings included on a pesticide's Preapproved Label, see 40 C.F.R. § 152.44(a), and the exceptions to the Preapproval Regulation would not permit the addition of the Cancer Warning to the Roundup label. This prohibition, we hold, imposes a "requirement" for the purposes of FIFRA's preemption provision. Because the Pa. Duty to Warn is not equivalent to that federal regulatory requirement, it is expressly preempted. Lastly, we explain in Part V why we are unpersuaded by the Schaffners' arguments that FIFRA cannot preempt a state-law duty to include a particular health warning on a pesticide's label by virtue of the omission of that warning on the pesticide's Preapproved Label.

I. Background[2]

A. FIFRA

FIFRA is a "comprehensive regulatory statute" that governs "the use, as well as the sale and labeling, of pesticides; regulate[s] pesticides produced and sold in both intrastate and interstate commerce; provide[s] for review, cancellation, and suspension of registration; and [gives the] EPA . . . enforcement authority." Ruckelshaus v. Monsanto Co., 467 U.S. 986, 991-92 (1984). FIFRA both regulates pesticides directly and grants the EPA additional authority to supervise the pesticide industry. One such direct regulation is FIFRA's prohibition on distributing or selling "any pesticide which is . . . misbranded." 7 U.S.C. § 136j(a)(1)(E). And one of the many ways in which a pesticide may be misbranded is for its label to omit "a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." Id. § 136(q)(1)(G). FIFRA thereby directly prohibits the distribution of pesticides whose labels fail to include warnings necessary to protect human health.

The pesticide registration process is among the methods through which FIFRA authorizes the EPA to supervise the pesticide industry. FIFRA prohibits the distribution or sale of any pesticide that has not been registered, id. § 136a(a), and it establishes procedures by which pesticides may be registered

[2] These facts, which are not materially disputed by the parties, are drawn from allegations in the complaint, as well as from documents issued by the EPA and other relevant public agencies.

with the EPA, see generally id. § 136a(c). An applicant for registration must first file with the EPA a statement containing information about the pesticide to be registered, including its formula and a complete copy of its proposed labeling, the "claims to be made for it," and the directions for its use. Id. § 136a(c)(1)(C)-(D). That statement must be accompanied by supporting data, as required by the EPA and by guidelines that FIFRA authorizes the EPA to promulgate. Id. § 136a(c)(2). The EPA registers the pesticide upon determining that it satisfies a number of conditions, including that its labeling complies with FIFRA's requirements. Id. § 136a(c)(5). The EPA further determines whether to classify the pesticide for general use or whether instead to restrict its use. Id. § 136a(d).

The information submitted to the EPA during a pesticide's registration process under FIFRA determines in part how the pesticide may be marketed following its registration. For example, when it is distributed or sold, a registered pesticide's composition may not differ from the composition described in the statement submitted as part of its application for registration. Id. § 136j(a)(1)(C). Similarly, the claims made for the pesticide as part of its distribution or sale may not differ substantially from the claims made for it in its registration statement. Id. § 136j(a)(1)(B). Most relevant here, unless certain exceptions apply, the Preapproval Regulation requires that an application for an amended registration be submitted when a registered pesticide's labeling is modified from its Preapproved Label. See 40 C.F.R. § 152.44(a) ("[A]ny modification in the . . . labeling . . . of a registered product must be submitted with an application for amended registration."). And the pesticide may not be distributed or sold with the modified label until the EPA approves the amended registration. See id. ("If an application for amended

registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.").

The EPA's supervision of a pesticide does not end once it approves an application to register that pesticide. In the 1988 amendments to FIFRA, see generally Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988, Pub. L. No. 100-532, 102 Stat. 2654, Congress required the EPA to reregister any pesticide (save for those falling within certain exceptions not relevant here) with an active ingredient contained in a pesticide first registered before November 1984. See 7 U.S.C. § 136a-1(a). And in the 2007 amendments to FIFRA, see generally Pesticide Registration Improvement Renewal Act, Pub. L. No. 110-94, 121 Stat. 1000 (2007), Congress required the EPA to conduct a registration review for each pesticide every fifteen years. See 7 U.S.C. § 136a(g). In addition, FIFRA obligates a registrant to inform the EPA if, following registration, it learns of new information concerning a pesticide's environmental risks. Id. § 136d(a)(2). The EPA may, on its own initiative, revisit its decision to register a pesticide should it conclude at any time that the pesticide can no longer meet the requirements for registration. See generally id. § 136d(b).

B. Roundup

In 1974, Monsanto introduced the pesticide Roundup, a weed-killer that employs glyphosate as its active ingredient. Since then, the EPA has repeatedly evaluated the health risks posed by glyphosate. It first assessed the carcinogenicity of glyphosate in 1985, when it classified the chemical as "possibly carcinogenic to humans." Joint Appendix ("JA") 43,

954. The following year, a scientific advisory panel concluded that glyphosate's human carcinogenicity could not yet be classified and suggested a review of additional data. Following the submission of further studies, in 1991 the EPA reclassified glyphosate as a chemical for which there exists "evidence of non-carcinogenicity for humans." JA 955. It has not altered that conclusion since. More recently, its Cancer Assessment Review Committee reviewed scientific data about glyphosate in 2015 and concluded that the pesticide was "not likely to be carcinogenic to humans." Id. And in January 2020, it issued an interim decision in its review of glyphosate's registration, finding once again that glyphosate is not likely to be carcinogenic to humans. That portion of the EPA's interim decision has since been vacated by the Court of Appeals for the Ninth Circuit. Nat. Res. Def. Council v. U.S. Env't Prot. Agency, 38 F.4th 34, 45 (9th Cir. 2022).

Others have disagreed with the EPA's view that glyphosate is not carcinogenic, however. The International Agency for Research on Cancer ("IARC"), which forms part of the World Health Organization, concluded in 2015 than glyphosate is probably carcinogenic to humans. See Kathryn Z. Guyton et al., Carcinogenicity of Tetrachlorvinphos, Malathion, Palathion, Diazinon, and Glyphosate, 16 Lancet Oncology 490 (2015) (announcing the IARC's conclusion); Int'l Agency for Rsch. on Cancer, World Health Org., IARC Monographs on the Evaluation of Carcinogenic Risks to Humans No. 112: Some Organophosphate Insecticides and Herbicides 321-99 (2017). The IARC further noted that non-Hodgkin's lymphoma is among the types of cancer most closely associated with glyphosate.

Following the IARC's announcement of its findings, plaintiffs across the United States began filing lawsuits against Monsanto to seek compensation for cancers allegedly caused by their use of Roundup. See In re Roundup Prods. Liab. Litig., 214 F. Supp. 3d 1346, 1348-49 (J.P.M.L. 2016) (listing actions filed as of October 3, 2016). In 2016, Monsanto moved to dismiss in one such case on the theory that any state-law duty to warn of Roundup's carcinogenicity was expressly preempted by FIFRA's preemption provision. See Mot. to Dismiss at 5-10, Hardeman v. Monsanto Co., No. 16 Civ. 525 (VC) (N.D. Cal. Mar. 1, 2016). The motion was denied in April of 2016. Hardeman v. Monsanto Co. (Hardeman I), 216 F. Supp. 3d 1037, 1038-39 (N.D. Cal. 2016).

In October 2016, the Judicial Panel on Multi-District Litigation ("JPML") responded to the growing wave of Roundup litigation by centralizing pretrial proceedings for lawsuits alleging that Roundup can cause non-Hodgkin's lymphoma and that Monsanto had failed to warn adequately of that risk. In re Roundup Prods. Liab. Litig., 214 F. Supp. 3d at 1347-48. As the venue for the MDL, the JPML chose the United States District Court for the Northern District of California (the "MDL Court") — the same court that had already heard, and rejected, Monsanto's express preemption argument.[3] Id. at 1348. The first bellwether trial was later held

[3] In addition to the argument described here, which was raised by Monsanto and rejected by the MDL Court in 2016, Monsanto raised a second express preemption argument in its January 2019 motion for summary judgment, which the MDL Court denied in March 2019. In re Roundup Prods. Liab. Litig., 364 F. Supp. 3d 1085, 1087 (N.D. Cal. 2019). That argument relied on details of California products liability law.

before the MDL Court featuring the same plaintiff, Edwin Hardeman, against whom Monsanto had first raised its express preemption arguments in 2016. See Hardeman v. Monsanto Co. (Hardeman II), 997 F.3d 941, 950 (9th Cir. 2021). At that trial, a jury found Monsanto liable for failing to warn of Roundup's carcinogenicity. Id. It awarded compensatory damages of over $5 million and punitive damages of $75 million, the latter of which were reduced to $20 million by the MDL Court. Id. Monsanto appealed that judgment on multiple grounds, including by challenging the MDL Court's rejection of its preemption arguments. Id. The Court of Appeals for the Ninth Circuit affirmed, holding that FIFRA did not preempt the California duty to warn that Monsanto was found liable for violating. Id. The Supreme Court denied Monsanto's petition for certiorari. Monsanto Co. v. Hardeman, 142 S. Ct. 2834 (2022).

While the JPML centralized pretrial proceedings for Roundup cases involving non-Hodgkin's lymphoma, cases involving other types of cancer remained in the districts in which they were filed. Among them is Carson v. Monsanto Co., which was filed in the Southern District of Georgia in December 2015, and which involves malignant fibrous histiocytoma rather than non-Hodgkin's lymphoma. See Carson v. Monsanto Co., (Carson I), 508 F. Supp. 3d 1369, 1373 (S.D. Ga. 2020). In Carson I, Monsanto moved for judgment on the pleadings using the same express-preemption arguments that the MDL Court had rejected in Hardeman I, and the district court dismissed the plaintiff's failure-to-warn claim on the grounds that it was expressly preempted by FIFRA. Id.

As the present case does not concern California law, Monsanto unsurprisingly has not raised that argument before this Court.

at 1375-76. The plaintiff appealed after amending his complaint to withdraw the claims that remained. See Carson v. Monsanto Co. (Carson II), 51 F.4th 1358, 1361 (11th Cir. 2022).[4] A panel of the Court of Appeals for the Eleventh Circuit reversed, holding that the district court had misapprehended the types of agency action that can preempt state law pursuant to FIFRA's express preemption provision. Id. at 1362-65. Sitting en banc, that court then vacated and remanded Carson II, holding that the panel had improperly relied on the law of implied preemption to analyze Monsanto's doctrinally distinct express-preemption arguments. Carson v. Monsanto Co. (Carson III), 72 F.4th 1261, 1267-68 (11th Cir. 2023) (en banc). The original panel then held, on remand, that the doctrines it had derived from implied-preemption precedents in Carson II also apply, independently, to express preemption under FIFRA. Carson v. Monsanto Co. (Carson IV), 92 F.4th 980, 992-93 (11th Cir. 2024). On that basis, the court reversed Carson I's holding that FIFRA expressly preempts failure-to-warn claims premised on Monsanto's failure to include the Cancer Warning on the Roundup label. Id. at 999.

C. The Schaffners

David Schaffner, Jr. was diagnosed with non-Hodgkin's lymphoma in 2006. Prior to his diagnosis, he was exposed to Roundup both in his work as a professional landscaper and in

[4] Carson II vacated and superseded an earlier opinion issued by the same panel in the same year. See Carson II, 51 F.4th at 1360, vacating Carson v. Monsanto Co., 39 F.4th 1334 (11th Cir. 2022). Because the two opinions differ only in minor ways, we will not further discuss the panel's initial opinion.

his capacity as a property owner. Theresa Sue Schaffner, his wife, suffered loss of consortium due to Mr. Schaffner's illness. In May 2019, the Schaffners filed a lawsuit against Monsanto in the Court of Common Pleas of Allegheny County, Pennsylvania, asserting six state-law causes of action, including one for failure to warn. Monsanto removed the case to the United States District Court for the Western District of Pennsylvania in October 2019, and the following month the JPML transferred the case to the Northern District of California. Because the MDL court had instructed the parties not to relitigate issues that it had already decided, Monsanto moved for summary judgment on preemption grounds merely by incorporating its earlier briefing before the MDL Court on that question, and the Schaffners opposed the motion on the same basis. The MDL Court denied the motion for the same reasons that it had relied upon in its earlier rejection of Monsanto's arguments. It then filed a suggestion of remand to the Western District of Pennsylvania, and the case was remanded to that court in March 2022.

Following the remand, the parties consented for all further proceedings in the District Court to be held before Chief Magistrate Judge Cynthia Reed Eddy pursuant to 28 U.S.C. § 636(c).[5] The Schaffners moved with Monsanto's consent to amend their complaint by removing all causes of action besides their claim for failure to warn, and the District Court granted that motion. The parties then jointly stipulated to the entry of judgment against Monsanto, with the express understanding that Monsanto reserved the right to appeal from — and intended to appeal from — the MDL Court's orders rejecting its preemption arguments. As the stipulation explained, while

[5] For ease of reference, we refer simply to the District Court.

the parties remained adverse and in disagreement with respect to those orders, they had reached a settlement with respect to all other aspects of the suit, and Monsanto had agreed to pay the Schaffners an amount that would depend on the ultimate result of the appeal. Pursuant to that stipulation, the District Court entered judgment in favor of the Schaffners. This timely appeal followed.

II. Jurisdiction and Standard of Review

The District Court had jurisdiction over the Schaffners' claims under 28 U.S.C. § 1332, and we have jurisdiction over Monsanto's appeal from the judgment entered against it under 28 U.S.C. § 1291. While that judgment was stipulated to by the parties, we held in Keefe v. Prudential Property & Casualty Insurance Co., 203 F.3d 218 (3d Cir. 2000), that we may exercise jurisdiction over an appeal from a stipulated judgment so long as the parties "are truly adverse with respect to the critical legal issue that they ask us to resolve, . . . the dispute between them is not feigned[,] . . . [and] both parties have a significant stake in the outcome." Id. at 224. We have reviewed the confidential settlement agreement between the parties to this case to verify that those conditions are met, and we are satisfied that we have jurisdiction.

In an appeal taken once "final judgment has been entered, . . . claims of district court error at any stage of the litigation may be ventilated." Dupree v. Younger, 598 U.S. 729, 734 (2023) (quoting Quackenbush v. Allstate Ins. Co., 517 U.S. 706, 712 (1996)). Monsanto's appeal therefore draws in question the MDL Court's order denying its motion for summary judgment on preclusion grounds. That order, in turn, incorporated by reference the MDL Court's prior order

rejecting certain of Monsanto's preclusion arguments with respect to other cases that also formed part of the MDL. And that earlier order itself incorporated by reference an even earlier order also rejecting Monsanto's preemption arguments, which the MDL Court issued in Hardeman before pre-trial proceedings in that case were centralized with others in the MDL. Consequently, the MDL Court's rulings on preemption are properly before us in this appeal. We review questions of preemption de novo. Sikkelee v. Precision Airmotive Corp., 822 F.3d 680, 687 (3d Cir. 2016).

III. The Effect of Hardeman II

Before considering Monsanto's contention that FIFRA preempts the Pa. Duty to Warn, however, we first address the Schaffners' two arguments that the Court of Appeals for the Ninth Circuit's rejection of Monsanto's position in Hardeman II binds us in this case. Schaffner Br. 47-55. Neither argument is compelling.

We begin with the law-of-the-case doctrine, under which "one panel of an appellate court generally will not reconsider questions that another panel has decided on a prior appeal in the same case." In re Phila. Litig., 158 F.3d 711, 717 (3d Cir. 1998). The Court of Appeals for the Ninth Circuit decided in Hardeman II that FIFRA does not preempt a state-law failure-to-warn claim premised on the omission of the Cancer Warning from Roundup's label. 997 F.3d at 954-60. The Schaffners therefore conclude that this Court should not reconsider the question. Schaffner Br. 53-54. The law-of-the-case doctrine, however, applies only when a question has been decided in "a prior appeal in the same case." In re Phila. Litig., 158 F.3d at 717 (emphasis added). As we recently held in

Home Depot USA, Inc. v. Lafarge North America, Inc., 59 F.4th 55 (3d Cir. 2022), "[c]ases centralized in an MDL 'retain their separate identities' unless they choose to proceed on a consolidated 'master' complaint," and the law-of-the-case doctrine therefore cannot be applied across distinct actions in an MDL. Id. at 61 (quoting Gelboim v. Bank of Am. Corp., 574 U.S. 405, 413 & n.3 (2015)). Because Hardeman and the present case remain distinct despite having been centralized in the same MDL, a holding issued in the former is not binding as the law of the case upon this Court.

We next turn to issue preclusion, which "prevents parties from relitigating an issue that has already been actually litigated." Peloro v. United States, 488 F.3d 163, 174 (3d Cir. 2007).[6] There are four general "prerequisites for the

[6] "[T]he law of the issuing court — here, federal law — determines the preclusive effects of a prior judgment." Peloro, 488 F.3d at 175 n.11 (quotation marks omitted). Nonetheless, in some contexts federal law provides that the preclusive effect of a federal-court judgment must follow state law rather than being determined independently as a matter of federal common law. In particular, the Supreme Court has held that the law of the state in which a federal court sits determines the claim-preclusive effect of the judgments that court issues pursuant to its diversity jurisdiction. Semtek Int'l Inc. v. Lockheed Martin Corp., 531 U.S. 497, 508 (2001). That principle could conceivably be extended to require state law also to determine the issue-preclusive effect of judgments issued by a federal court sitting in diversity, such as the judgment issued in Hardeman II. See, e.g., CSX Transp., Inc. v. Gen. Mills, Inc., 846 F.3d 1333, 1340 (11th Cir. 2017). But because the parties have each framed their arguments concerning issue preclusion

application of issue preclusion": "(1) the issue sought to be precluded is the same as that involved in the prior action; (2) that issue was actually litigated; (3) it was determined by a final and valid judgment; and (4) the determination was essential to the prior judgment." Nat'l R.R. Passenger Corp. v. Pa. Pub. Util. Comm'n, 288 F.3d 519, 525 (3d Cir. 2002) (cleaned up). The Schaffners argue that each of these four is met, Schaffner Br. 49-52, and Monsanto does not appear to dispute the point, see Monsanto Reply 21-26.

Even when those four prerequisites are met, however, issue preclusion "is subject to a number of equitable exceptions designed to assure that the doctrine is applied in a manner that will serve the twin goals of fairness and efficient use of private and public litigation resources." Nat'l R.R. Passenger Corp., 288 F.3d at 525. The scope of a court's equitable discretion depends on whether all parties to the subsequent case were also parties to the prior one, which is referred to as mutuality, and on whether preclusion favors the plaintiff or the defendant in

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using this Court's own precedents, not California law, see Schaffner Br. 48-49; Monsanto Reply 21-26, we decline to consider whether California law should govern. See Williams v. BASF Catalysts LLC, 765 F.3d 306, 316 (3d Cir. 2014) (holding that by briefing and relying on one sovereign's law, a party waives any argument that the law of a different sovereign should apply, as while "litigants may not waive issues that go to the power of the courts to hear a case," "choice-of-law questions do not go to the court's jurisdiction"); Hammersmith v. TIG Ins. Co., 480 F.3d 220, 227 n.2 (3d Cir. 2007) ("Because the parties only argued the choice-of-law issue with respect to New York and Pennsylvania, we will not consider Texas in our choice-of-law analysis.").

the second suit, which distinguishes offensive uses of preclusion from defensive ones. Id. The application of issue preclusion in favor of the Schaffners would be offensive and non-mutual, as the Schaffners are the plaintiffs, and they were not parties in Hardeman. Courts enjoy particularly broad discretion in deciding whether to employ issue preclusion in offensive, non-mutual contexts. Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc., 458 F.3d 244, 249 (3d Cir. 2006) (citing Parklane Hosiery Co. v. Shore, 439 U.S. 322, 331 (1979)).

To identify which equitable factors should guide a court's application of issue preclusion in general, we have relied upon the relevant provisions of the Restatement (Second) of Judgments ("Second Restatement"), see, e.g., Nat'l R.R. Passenger Corp., 288 F.3d at 525, as has the Supreme Court, see, e.g., Standefer v. United States, 447 U.S. 10, 23 & n.17, 25 (1980). The specific factors to be applied in cases of non-mutual issue preclusion, offensive or defensive, are identified in section 29 of the Second Restatement. Monsanto argues that one such factor weighs decisively against applying issue preclusion to its preemption arguments. Whether FIFRA preempts a state-law duty to provide a health warning given the omission of that warning from a pesticide's Preapproved Label is a pure question of law. And in cases of non-mutual issue preclusion one of the "circumstances [that] justify affording [a party] an opportunity to relitigate the issue" sought to be precluded is that "[t]he issue is one of law and treating it as conclusively determined would inappropriately foreclose opportunity for obtaining reconsideration of the legal rule upon which it was based." Restatement (Second) of Judgments § 29(7) (Am. L. Inst. 1982). Applying issue preclusion to a pure question of law, the Second Restatement

reasons, risks impeding a court from discharging "its function of developing the law." Id. cmt. i. Furthermore,

> This consideration is especially pertinent when . . . the issue was determined in an appellate court whose jurisdiction is coordinate with or subordinate to that of an appellate court to which the second action can be taken; or when the issue is of general interest and has not been resolved by the highest appellate court that can resolve it.

Id. The Second Restatement therefore advises that "the rule of preclusion should ordinarily be superseded" when either of those circumstances is present. Id.

These principles have been applied by multiple other United States Courts of Appeals, see, e.g., In re Westmoreland Coal Co., 968 F.3d 526, 532 (5th Cir. 2020); Pharm. Care Mgmt. Ass'n v. District of Columbia, 522 F.3d 443, 446-47 (D.C. Cir. 2008); Af-Cap, Inc. v. Chevron Overseas (Congo) Ltd., 475 F.3d 1080, 1086 (9th Cir. 2007); Chi. Truck Drivers, Helpers, & Warehouse Union (Indep.) Pension Fund v. Century Motor Freight, Inc., 125 F.3d 526, 531 (7th Cir. 1997), as well as by the highest courts of multiple states, see Planned Parenthood of the Heartland, Inc. v. Reynolds ex rel. State, 975 N.W.2d 710, 729-30 (Iowa 2022); NIPSCO Indus. Grp. v. N. Ind. Pub. Serv. Co., 100 N.E.3d 234, 244-45 (Ind. 2018); Bowen ex rel. Doe v. Arnold, 502 S.W.3d 102, 117 (Tenn. 2016). And we are unaware of any decision of such a court that has considered these principles and either rejected them as invalid or expressly declined to apply them to facts analogous to those before us now. We join this consensus and hold that

section 29(7) of the Second Restatement, along with its elaboration in comment i to that section, identifies an equitable factor that courts may consider in deciding whether to apply issue preclusion non-mutually. Applying the principles articulated in that section, we conclude that both circumstances requiring that "the rule of preclusion should ordinarily be superseded," Restatement (Second) of Judgments § 29 cmt. i, are present. The appellate courts to which appeals were taken in Hardeman and in this case — respectively, the Court of Appeals for the Ninth Circuit and this Court — have coordinate jurisdiction. See Hoffman v. Blaski, 363 U.S. 335, 340 n.9 (1960). And the issue presented by this case, which is clearly of general interest, has yet to be decided by the highest court capable of resolving it — the United States Supreme Court. We therefore follow the Second Restatement in exercising our "broad discretion to determine when to apply non-mutual offensive [issue preclusion]." Jean Alexander Cosmetics, 458 F.3d at 249. We decline to apply issue preclusion and instead develop the law of express preemption under FIFRA ourselves.[7]

IV. Express Preemption Under FIFRA

The provision of FIFRA governing "uniformity" provides that no state shall "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C.

[7] In addition, one Justice of the Supreme Court has expressed "serious doubts about the application of nonmutual offensive [issue preclusion] in the MDL context." See E.I. du Pont de Nemours & Co. v. Abbott, 144 S. Ct. 16, 16 (2023) (Thomas, J., dissenting from denial of petition for writ of certiorari).

§ 136v(b). Monsanto argues that because Roundup's Preapproved Label omitted the Cancer Warning, any state-law requirement to include it on the Roundup label is "in addition to or different from" the labeling requirements imposed under FIFRA, and thus is preempted.[8] Monsanto Br. 25-47. We begin our analysis by discussing the principles the Supreme Court has articulated to govern whether a suit under state law is preempted by section 136v(b).

In Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005), the Supreme Court held that a requirement imposed under state law must meet two conditions to be preempted by section 136v(b). Id. at 444. "First, it must be a requirement '*for labeling or packaging*,'" and "[s]econd, it must impose a labeling or packaging requirement that is '*in addition to or different from* those required under this subchapter.'" Id. (quoting 7 U.S.C. § 136v(b)). The Court further held that a common-law duty to warn satisfies the first of these two conditions, constituting a requirement for labeling or packaging because it "set[s] a standard for a product's labeling that the . . . label is alleged to have violated by containing . . . inadequate warnings." Id. at 446. Although the Schaffners argued otherwise in their briefing, see Schaffner Br. 28-29, at oral argument they conceded that under this principle the Pa. Duty to Warn constitutes a "requirement for labeling or packaging," Oral Arg. at 18:00-18:46. The first of the two

[8] Monsanto also argues that the Pa. Duty to Warn is preempted under the doctrine of impossibility preemption, which applies when state and federal law impose inconsistent obligations that cannot be jointly discharged. Monsanto Br. 47-57. Because we conclude that FIFRA expressly preempts the Pa. Duty to Warn, we need not consider this alternative theory.

conditions required for section 136v(b) to apply is therefore met. The sole question that remains is whether the second is met as well — that is, whether the Pa. Duty to Warn is in addition to or different from the requirements imposed under FIFRA itself.

To answer that question, we follow the approach outlined in Bates, where the Supreme Court explained how courts must determine whether a state-law requirement is preempted under section 136v(b) because it is "in addition to or different from" the requirements imposed under FIFRA. 544 U.S. at 447. That language, the Court held, imposes a "parallel requirements" test. Id. Under that test, a state-law labeling requirement is not preempted if it is "equivalent to a requirement under FIFRA," while it is preempted if it "diverges from those set out in FIFRA and its implementing regulations." Id. at 452-53. Section 136v(b) does not preclude states from awarding remedies — such as monetary damages — against those whose conduct breaches a requirement imposed under FIFRA, even if FIFRA does not itself authorize such remedies. Id. at 448. But it does not allow states to impose liability on those who would not otherwise be liable for violating a requirement under FIFRA. Id. at 454. Consequently, to apply the parallel-requirements test, a court must identify the labeling requirements imposed under state law and under FIFRA, then compare the two to determine whether a pesticide label that violates the state requirement would also violate the federal one. Id. If so, the state-law requirement is equivalent to the federal one and is not preempted. Id. If not, the requirements are not equivalent, and the federal requirement preempts the state one. Id.

The parties' primary disagreement in this case lies in how they identify the federal requirement that must be compared with the Pa. Duty to Warn in applying the parallel-requirements test (the "Federal Comparator"). The parties do not challenge each other's interpretation of the Pa. Duty to Warn, nor do they analyze equivalence differently between it and the Federal Comparator once the latter is identified. See Monsanto Br. 37-39; Schaffner Br. 30-31. To decide this case, then, we must first determine the content of the Federal Comparator, then apply the parallel-requirements test by comparing it with the Pa. Duty to Warn.

According to the Schaffners, the Federal Comparator incorporates only FIFRA's statutory prohibition on misbranding. Schaffner Br. 29. FIFRA prohibits the distribution or sale of a pesticide that is "misbranded," 7 U.S.C. § 136j(a)(1)(E), and it defines a pesticide as misbranded if its label "does not contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." Id. § 136(q)(1)(G). Pennsylvania products liability law deems a product "defective," in turn, 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., 665 A.2d 1167, 1171 (Pa. 1995). The Schaffners argue that FIFRA does not preempt the Pa. Duty to Warn because Pennsylvania's standard for defective products is equivalent to FIFRA's statutory misbranding standard. Schaffner Br. 29-31. Crediting the allegation that the omission of the Cancer Warning from Roundup's label rendered the pesticide defective, its label arguably lacked a warning "necessary . . . to protect health" and thereby satisfied the statutory definition of misbranding, see 7 U.S.C. § 136(q)(1)(G); Schaffner Br. 29-31. Applying

the parallel-requirements test in this fashion, the Courts of Appeals for the Ninth and Eleventh Circuits each held that section 136v(b) does not preempt the similar duties to warn imposed by California and Georgia law. See Carson IV, 92 F.4th at 991-92; Hardeman II, 997 F.3d at 955-56.

Monsanto argues instead that the Federal Comparator must incorporate the Preapproval Regulation, 40 C.F.R. § 152.44(a), and through it the EPA's repeated approvals of proposed Roundup labels omitting the Cancer Warning. Monsanto Br. 28-30. As set forth above, FIFRA both prohibits the distribution or sale of unregistered pesticides and institutes a process through which the EPA registers individual pesticides once it has determined that those pesticides, and their proposed labels, comply with FIFRA. See generally 7 U.S.C. § 136a. The EPA established that federal law requires Roundup's label to omit the Cancer Warning, in Monsanto's view, since its Preapproved Label omits the Cancer Warning. Monsanto Br. 28-30. And if FIFRA requires the Cancer Warning to be omitted, a Roundup label that complies with FIFRA must violate the Pa. Duty to Warn. Monsanto therefore concludes that the Pa. Duty to Warn is not equivalent to the Federal Comparator, that the parallel-requirements test is not met, and that the Pa. Duty to Warn is preempted under section 136v(b). Id. at 37-38.

Must the Pa. Duty to Warn be equivalent to a Federal Comparator incorporating only the requirement that pesticides not be misbranded under the statutory definition of that term, as the Schaffners claim? Or must it be equivalent to a Federal Comparator also incorporating the omission of the Cancer Warning from Roundup's Preapproved Label, as Monsanto claims? This dispute, which lies at the core of the parties'

disagreement, forms the focus of our analysis in this opinion. EPA regulations govern different parts of a pesticide label differently, so our holding does not generalize to all state-law claims involving pesticide labeling. But with respect to the Cancer Warning, we hold that Monsanto is correct.

Our analysis proceeds in three steps. First, in Part IV(A), we examine "EPA regulations that give content to FIFRA's misbranding standards."[9] Bates, 544 U.S. at 453. We

[9] The Supreme Court has recently overruled its decision in Chevron U.S.A., Inc. v. National Resources Defense Council, 467 U.S. 837 (1984), holding that "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority." Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2273 (2024). Prior to Loper Bright, courts might have owed deference to the EPA's interpretation of the statutory term "misbranding," but no more. Nonetheless, while Loper Bright requires courts, not agencies, to determine the meaning of statutory terms such as "misbranding," we do not read the decision to undermine the EPA's authority to promulgate the regulations that implement FIFRA. As the Court explained in Loper Bright, while courts alone must ascertain a statute's meaning, "the statute's meaning may well be that the agency is authorized to exercise a degree of discretion." Id. at 2263. And one way for statutes to express that meaning is when they "empower an agency to prescribe rules to 'fill up the details' of a statutory scheme." Id. (quoting Wayman v. Southard, 23 U.S. (10 Wheat.) 1, 43 (1825)). FIFRA is such a statute: it expressly authorizes the EPA Administrator "to prescribe regulations to carry out the provisions" of the statute. 7 U.S.C. § 136w(a)(1). We therefore conclude that Loper Bright does not undermine the

conclude that the Preapproval Regulation, 40 C.F.R. § 152.44, prohibited Monsanto from modifying Roundup's Preapproved Label in order to add the Cancer Warning. Second, in Part IV(B), we consider whether the Preapproval Regulation establishes a "requirement" for the purposes of preemption under section 136v(b), and we conclude that it does. Third, in Part IV(C), we return to the parallel-requirements test. Having held that the Preapproval Regulation constitutes a "requirement" under section 136v(b), we must decide whether to apply the parallel-requirements test by comparing the Pa. Duty to Warn with a Federal Comparator that incorporates that regulatory requirement, or whether instead to compare the Pa. Duty to Warn with a Federal Comparator that incorporates the requirement that pesticides not be misbranded solely under the statutory definition of that term. Under the parallel-requirements test, state-law requirements must "be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." Bates, 544 U.S. at 453. We therefore hold that the parallel-requirements test must involve a comparison to the Preapproval Regulation, and having so held we apply the test. While the Cancer Warning was allegedly required by the Pa. Duty to Warn, it was omitted from Roundup's Preapproved Label and could not have been added to the Roundup label without violating the Preapproval Regulation. Accordingly, the Pa. Duty to Warn is not equivalent to the Federal Comparator, and it is thus preempted under section 136v(b).

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validity of the EPA regulations that govern pesticide labeling and that we consider in analyzing preemption under FIFRA in this opinion.

A. Modifications to Pesticide Labels

FIFRA "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." Bates, 544 U.S. at 452 (emphasis added). We thus first examine the EPA regulations that govern pesticide labeling under FIFRA. FIFRA authorizes the EPA Administrator "to prescribe regulations to carry out the provisions of this subchapter." 7 U.S.C. § 136w(a)(1). Pursuant to that authority, the EPA has promulgated regulations that govern both the process of initially registering a pesticide and the process of subsequently amending its registration. See generally 40 C.F.R. pt. 152, subpt. C. As noted above, the Preapproval Regulation mandates that "[e]xcept as provided by § 152.46, any modification in the . . . labeling . . . of a registered product must be submitted with an application for amended registration." Id. § 152.44(a). And "[i]f an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold." Id. Once a pesticide is registered and its proposed label is approved by the EPA, then, the Preapproval Regulation prohibits the distribution or sale of the pesticide with a modified label, unless and until an application for amended registration is submitted and approved.

The Preapproval Regulation contains an exception, however. Only "[i]f an application for amended registration is required" must an application for amended registration be approved before the modified pesticide may be sold or distributed. Id. And such an application is not always required.

Modifications may be made without an application for amended registration "as provided by § 152.46." Id. That section governs the modification of a pesticide or its label "by notification," a procedure under which the registrant must inform the EPA of the modification but need not receive approval before selling or distributing the modified pesticide.[10] Id. § 152.46(a). The Schaffners argue that adding the Cancer Warning to the Roundup label would be a permissible modification by notification under section 152.46. Schaffner Br. 46-47. Were they correct, no application for amended registration would be required, and the Preapproval Regulation would by its own terms have permitted Monsanto to add the Cancer Warning.

The Schaffners rely on section 152.46's provision that "a manufacturer can make minor modifications to labeling that have 'no potential to cause unreasonable adverse effects to the environment' without prior EPA approval if EPA is notified of the change." Schaffner Br. 46 (quoting 40 C.F.R. § 152.46(a)(1)). Monsanto could have relied on this authorization, they suggest, to add the Cancer Warning to the Roundup label using modification by notification. Id. The Schaffners quote the phrase out of context, however. Section 152.46 does not itself directly permit the modification by notification of a registered pesticide in any manner that has "no

[10] Section 152.46 also governs the modification of a pesticide "without notification," in which case the label may be changed without any EPA involvement. 40 C.F.R. § 152.46(b). Because the Schaffners do not argue that the Roundup label could have been modified without notification, however, see Schaffner Br. 46-47, we focus only upon modification by notification.

potential to cause unreasonable adverse effects to the environment." 40 C.F.R. § 152.46(a)(1). Rather, it merely authorizes the EPA, at its discretion, to permit registrants to modify pesticides by notification in some such circumstances:

> 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 Agency, without requiring that the registrant obtain Agency approval. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of modifications permitted by notification and any conditions and procedures for submitting notifications.

40 C.F.R. § 152.46(a)(1) (emphasis added). Thus, section 152.46(a) does not of its own force permit Monsanto to add the Cancer Warning to the Roundup label by notification. At most, it could authorize the EPA to permit that modification to be made by notification. Whether Monsanto in fact could have added the Cancer Warning by notification depends on how the EPA has exercised the authority conferred upon it by section 152.46(a).

We therefore turn to the policies that the EPA has issued pursuant to its authority under section 152.46(a)(1). Following the opportunity for public comment required by section 152.46(a), see Proposed Pesticide Amendment Reinvention Measures, 62 Fed. Reg. 51467 (Oct. 1, 1997), in 1998 the EPA issued Pesticide Registration Notice 98-10 ("PRN 98-10"), see generally JA 142-64, on the subject of "Notifications, Non-

Notifications and Minor Formulation Amendments," JA 142. Pursuant to the EPA's authority under section 152.46, PRN 98-10 specifies which "registration amendments may be accomplished by notification" as pertains to "labeling." JA 144. But PRN 98-10 does not allow the Cancer Warning to be added by notification. PRN 98-10 explicitly enumerates what types of modifications may be made by notification, and that list includes no category that might encompass the addition of the Cancer Warning to a pesticide label. See JA 144-50, 162-64. Instead, the final item on that list — a catch-all provision encompassing minor label changes that do not fall under any earlier item — expressly provides that modification by notification must "involve no change in . . . precautionary statements." JA 150. The Cancer Warning would constitute a precautionary statement because it would at a minimum "describe[e] the particular hazard," along with whatever other information it might contain.[11] 40 C.F.R. § 156.70(b); see also

[11] In certain contexts, the EPA distinguishes between a "hazard statement" and a "precautionary statement," though in others it uses "precautionary statement" in a manner that reaches across that distinction. See 40 C.F.R. § 156.60 ("Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects."); but see id. § 156.70(b) (discussing "precautionary statements describing the particular hazard"); Office of Pesticide Programs, U.S. Env't Prot. Agency, Label Review Manual § 7.I, at 7-2 (2018) ("[P]recautionary statements provide the pesticide user with information regarding the toxicity, irritation, and dermal sensitization hazards associated with the use of the pesticide . . . ."). Because the EPA also employs the term "precautionary statements" as a heading for the section of the

Office of Pesticide Programs, U.S. Env't Prot. Agency, Label Review Manual § 7.I, at 7-2 (2018) ("[P]recautionary statements provide the pesticide user with information regarding the toxicity, irritation, and dermal sensitization hazards associated with the use of the pesticide . . . ."). Because adding the Cancer Warning would involve "a change . . . in precautionary statements," PRN 98-10 does not permit it to be added through modification by notification.[12]

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label that must contain all hazard and precautionary statements together, 40 C.F.R. § 156.70(a) ("Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading 'Precautionary Statements' . . . ."), we understand PRN 98-10's reference to "precautionary statements" to encompass any label contents properly placed under the heading "Precautionary Statements," regardless of whether those contents might be more precisely categorized as hazard statements or precautionary statements.

[12] Citing an instance in which the EPA condoned the addition of a cancer warning by notification, the Hardeman II court concluded that PRN 98-10 permits similar such warnings to be added by notification. 997 F.3d at 959-60, 959 n.10 (quoting Letter from Jennifer Gaines, EPA, Office of Pesticide Programs, to Larry Hodges, Bayer CropScience (Dec. 17, 2012)). But on that occasion, the warning, which read, "This product contains a chemical known to the state of California to cause cancer," was not placed beneath the heading "Precautionary Statements." Bayer CropScience, Proposed Larvin Label 2 (Nov. 29, 2012), https://www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf [https://perma.cc/5U8W-Y6QW]. Instead, it was included with legal information such as

warranty disclaimers, limitations of liability, and trademark registrations. Id. at 3.

The EPA understandably accepted the proposed modification as non-precautionary legal information, since the substance of that modification was to provide pesticide users with information about a determination made under California law. That is readily distinguishable from the Cancer Warning here, the substance of which is the finding of carcinogenicity itself. Put more simply, the Schaffners conflate the legal information that a state has made a particular determination with the non-legal substance of that determination, which, in our view, is clearly precautionary. Thus, unlike the notice considered by the court in Hardeman II, the Cancer Warning is not "minor" information that may be added by notification under PRN 98-10, and Monsanto could not have added it without running afoul of the Preapproval Regulation.

More generally, we also do not believe that courts may avoid the task of interpreting sources of law such as section 152.46 and PRN 98-10 based on the reasoning that actions must be permissible if the agency that administers that law has permitted them. See Hardeman II, 997 F.3d at 959. As the Supreme Court has recently reminded us, "[i]t is emphatically the province and duty of the judicial department to say what the law is." Loper Bright, 144 S. Ct. at 2257 (alteration in original) (quoting Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803)). And while courts may sometimes defer to an agency's interpretation of its own regulations, the Court has "cabined" the scope of that deference "in varied and critical ways." Kisor v. Wilkie, 588 U.S. 558, 580 (2019). Agency interpretations are not entitled to deference unless they

This interpretation of PRN 98-10 is further reinforced by the EPA regulation governing "[p]recautionary statements for human hazards," which provides that "[s]pecific statements pertaining to the hazards of the product and its uses must be approved by the Agency." Id. § 156.70(c). As the Cancer Warning would warn that Roundup risks causing a particular disease, it constitutes a "[s]pecific statement pertaining to the hazards of [Roundup] and its uses." It thus "must be approved by the Agency." See also JA 1045 (identifying a cancer warning for glyphosate-based pesticides that "could be approved, if requested by a pesticide registrant, for inclusion on pesticide labels" (emphasis added)). Label modifications made by notification, however, are accomplished "without requiring that the registrant obtain Agency approval." Id.

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emanate "from those actors, using those vehicles, understood to make authoritative policy in the relevant context." Id. at 577. Similarly, "an agency's reading of a rule must reflect 'fair and considered judgment' to receive . . . deference" from courts. Id. at 579 (quoting Christopher v. SmithKline Beecham Corp., 567 U.S. 142, 155 (2012)). The EPA letter cited in Hardeman II satisfies neither condition. Rather than being a statement of "authoritative policy," it merely condones a single registrant's modification by notification of the label of a single pesticide. See Letter from Jennifer Gaines. And rather than reflecting the EPA's "fair and considered judgment," it consists entirely of a single, boilerplate, three-sentence paragraph that omits any substantive analysis of PRN 98-10 or the relevant regulations. Id. Such a letter is not entitled to deference in the face of our conclusion, based on our own substantive legal analysis, that the Cancer Warning could not have been added to the Roundup label via modification by notification.

§ 152.46(a)(1). Because 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 Agency." Section 156.70 therefore provides an additional basis, besides the express terms of PRN 98-10 itself, for our conclusion that the Cancer Warning could not have been added to the Roundup label through modification by notification.

The present version of section 152.46 was enacted in 1996. See Notification Procedures for Pesticide Registration Modifications, 61 Fed. Reg. 33039, 33041 (June 26, 1996) (codified at 40 C.F.R. § 152.46). The Schaffners' earliest allegation of Mr. Schaffner's Roundup use dates to 1988, however, so the present version of section 152.46 did not apply during part of the period when the omission of the Cancer Warning allegedly caused Mr. Schaffner's illness — namely, the time prior to 1996. But the EPA regulations that applied prior to 1996 similarly prohibited Monsanto from adding the Cancer Warning to the Roundup label. While the present version of section 152.46 was enacted in 1996, the relevant portion of the Preapproval Regulation has been in force since 1988, prohibiting modifications to a registered pesticide without an approved application for amended registration unless the exception under section 152.46 applies. See Pesticide Registration Procedures; Pesticide Data Requirements, 53 Fed. Reg. 15952, 15978 (May 4, 1988) (codified at 40 C.F.R. § 152.44(a)); accord 40 C.F.R. § 152.44(a) (1996). And the earlier version of section 152.46, which was also promulgated in 1988, provided that modification by notification could be used for "[a] revision of the label language" only if it "involve[ed] no change in the . . . precautionary statements." Pesticide Registration

Procedures, 53 Fed. Reg. at 15978 (codified at 40 C.F.R. § 152.46(a)(1)); accord 40 C.F.R. § 152.46(a)(1) (1996) (superseded text); see also supra note 11. Before those regulations took effect, label changes could not be made absent EPA approval. See 40 C.F.R. § 162.6(b)(3) (1988) ("(i) *General*. Applications for amended registration shall be submitted if: (A) Changes are proposed in the labeling . . . . (iv) *Distribution under amended labeling*. (A) Approval of amendments authorizes distribution under such amended labeling . . . .").

Because the addition of the Cancer Warning to Roundup's label would involve a change in the precautionary statements on its Preapproved Label, modification by notification was unavailable under section 152.46 and PRN 98-10. The Preapproval Regulation therefore prohibited the addition of the Cancer Warning to the Roundup label without further EPA approval.

B. Requirements Under FIFRA

Roundup's Preapproved Label omitted the Cancer Warning, and the Preapproval Regulation prohibited Monsanto from modifying Roundup's label to include it.[13] Section

[13] 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. 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 Schaffners advanced no such

136v(b) preempts only those state-law requirements that are not parallel to any "requirement" imposed under FIFRA, however. The Preapproval Regulation could be relevant to the parallel-requirements test, and thereby to preemption under section 136v(b), only if it establishes a "requirement" under FIFRA. We next consider whether it establishes such a requirement, and we hold that it does.

First, the Preapproval Regulation satisfies the definition of "requirement" that the Supreme Court adopted in Bates. "A requirement is a rule of law that must be obeyed." Bates, 544 U.S. at 445. And "[r]ules issued through the notice-and-comment process," such as section 152.44(a), "have the force and effect of law." Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 96 (2015) (quotation marks omitted); see also Pesticide Regulation Procedures; Pesticide Data Requirements, 53 Fed. Reg. 15952, 15952-53 (May 4, 1988) (describing notice-and-comment proceedings undertaken prior to the promulgation of the Preapproval Regulation). The Preapproval Regulation is a rule of law that must be obeyed, so it establishes a "requirement" that a pesticide's label must conform to its Preapproved Label. Furthermore, because the Preapproval Regulation was enacted to "revise[] procedures for the registration of pesticide products under section 3 of [FIFRA]," Pesticide Regulation Procedures, 53 Fed. Reg. at 15952, it was promulgated under the EPA Administrator's authority "to prescribe regulations to carry out the provisions of [FIFRA]," 7 U.S.C. § 136w(a)(1). The regulatory prohibition on modifying a pesticide's Preapproved Label therefore constitutes a "require[ment] under [FIFRA]." Id. § 136v(b).

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argument here, however, we do not consider it, and we express no opinion as to whether it could succeed.

Indeed, in Bates the Supreme Court expressly identified EPA regulations as a source of "requirements" for the purposes of preemption under FIFRA. 544 U.S. at 452-54.

To be sure, while some EPA regulations directly identify the contents that labels must contain, the Preapproval Regulation instead only requires a pesticide's label to bear the contents contained in its Preapproved Label, whatever those contents may be. The regulation itself does not directly identify any particular label contents as permitted, prohibited, or required. In Bates, the Court's analysis suggested that a "requirement" under section 136v(b) must substantively restrict the content of pesticide labels. A state-law claim for breach of an express warranty that was included on a pesticide's label, it held, would not be preempted under FIFRA. 544 U.S. at 444-45. The duty to honor an express warranty placed on a pesticide label "does not impose a requirement 'for labeling or packaging'" because it "does not require the manufacturer to make an express warranty" on its label or "to say anything in particular in that warranty." Id. It might be argued, then, that the Preapproval Regulation fails to substantively restrict the content of pesticide labels, like the claim discussed in Bates, such that it fails to impose a "requirement" for the purposes of section 136v(b).

A state-law duty to honor an express warranty included on a pesticide label fails to impose a "requirement" for the purposes of section 136v(b), on the Court's reasoning, because that duty allows a registrant to include any language it wishes on a pesticide's label. In theory, the same could be true of the Preapproval Regulation. If the EPA automatically approved any proposed pesticide label without reviewing its contents in whole or in part, then the Preapproval Regulation would fail to

restrict substantively the contents of pesticide labels. A registrant could include any language it wished on a pesticide label simply by submitting a proposed label containing that language, then including it on the label following the proposal's automatic approval. But the EPA does not approve proposed labels automatically. Rather, it reviews the substance of proposed labels and approves them only if they "comply with the requirements of [FIFRA]," 7 U.S.C. § 136a(c)(5)(B), which requires the EPA to have "determined that the product is not misbranded as that term is defined in FIFRA," 40 C.F.R. § 152.112(f). Unlike the contractual obligation to honor an express warranty, the Preapproval Regulation does not permit a registrant to include whatever language it wishes on a pesticide label. Instead, because the EPA will approve only labels that it deems compliant with federal law, the prohibition on modifying a pesticide's Preapproved Label does "require the manufacturer . . . to say [some]thing in particular" on the pesticide label, Bates, 544 U.S. at 445 — namely, to include only content that the EPA deems compliant with federal law. The Preapproval Regulation therefore does impose a "requirement" under the principles articulated in Bates.

Our holding that the Preapproval Regulation imposes a "requirement" for purposes of preemption receives further support from the Supreme Court's preemption analysis in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). Riegel did not directly concern FIFRA or any of its provisions, including section 136v(b). Instead, in Riegel the Court analyzed preemption under the Medical Device Amendments of 1976 (the "MDA"), Pub. L. No. 94-295, 90 Stat. 539. 552 U.S. at 315. But FIFRA resembles the MDA in two respects that were central to the Court's preemption analysis in Riegel. First, the MDA's preemption provision prohibits states from imposing a

requirement for a medical device "which is different from, or in addition to, any requirement applicable under this chapter to the device," 21 U.S.C. § 360k(a)(1); see Riegel, 552 U.S. at 316, closely echoing the language employed by FIFRA's preemption provision, see 7 U.S.C. § 136v(b) (prohibiting states from imposing "requirements for labeling or packaging in addition to or different from those required under this subchapter"). Second, the defendant in Riegel argued that state law was preempted by a federal regulatory scheme — the MDA's system of premarket approval — that operates very similarly to pesticide registration under FIFRA. 552 U.S. at 315-20. A medical device cannot enter the market, unless certain exceptions apply, until it has received premarket approval, 21 U.S.C. § 360e(a), which must be denied unless the FDA concludes there is reasonable assurance of the device's safety, id. § 360e(d)(2)(A). Then, once premarket approval has been granted, a supplemental application for premarket approval is required before the device may be modified. Id. § 360e(d)(5)(A)(i). Like pesticides, medical devices must be reviewed and approved before being marketed, and once approved they cannot be modified unless the proposed modification is itself reviewed and approved.

Because the Court's decision in Riegel turned on the preemptive effect of a regulatory scheme similar to the system of pesticide registration created by FIFRA, and because the two statutes' preemption provisions themselves are so similar, the Court's analysis in that case sheds light on how we should analyze preemption under FIFRA. In Riegel, the Court applied the parallel-requirements test (in substance if not in name), just as we must do here, by separately identifying federal and state "requirements," then comparing them to determine whether they were equivalent. 552 U.S. at 321-22; see also Bates, 544

U.S. at 447-48 (relying on precedents interpreting the MDA in holding that the parallel-requirements test governs preemption under FIFRA). To "determine whether the Federal Government ha[d] established requirements applicable to" the challenged device, Riegel, 552 U.S. at 321, the Court focused on the MDA's system for premarket approval, analyzing in particular whether the prohibition on modifying a medical device once the FDA had reviewed and approved it for safety established a "requirement" for the purposes of preemption under the MDA. Id. at 322-23. And its conclusions and reasoning shed light on whether, in general, a "requirement" exists within the meaning of a similar preemption provision, such as FIFRA's, where an agency reviews regulated products for safety before they may be marketed, then prohibits modifications of those products absent an additional safety review.

The Court held in Riegel that premarket approval does establish "requirements" for purposes of the MDA's preemption provision. Id. at 322 ("Premarket approval . . . imposes 'requirements' under the MDA . . . ."). Its holding rested squarely on the two regulatory elements common to both premarket approval under the MDA and pesticide registration under FIFRA — namely, the safety review that regulated products must undergo before they are marketed, and the prohibition on subsequent modifications of such products once they are reviewed and approved. As the Court explained, "the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness," and "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that

the approved form provides a reasonable assurance of safety and effectiveness." Id. at 323. The process of premarket approval substantively restricts which medical devices may be sold by requiring a reasonable assurance of safety and effectiveness, the Court reasoned, and therefore the preapproval regulations limiting modifications to a medical device that has received premarket approval also substantively restrict which medical devices may be sold. No requirement would have existed were medical devices permitted to "take any particular form for any particular reason." Id. (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996)); see also Lohr, 518 U.S. at 492-94. But a requirement existed for purposes of preemption because a medical device must take a certain specific form following premarket approval.

The analysis of "requirements" adopted in Riegel carries over to FIFRA. If the prohibition on modifying medical devices following their approval for safety establishes "requirements" for medical devices, then FIFRA's regulatory approach, which employs the same two elements, should likewise establish "requirements" under a similar preemption provision, such as section 136v(b) of FIFRA. Laws fail to establish requirements if they do not require registered products to "take any particular form for any particular reason." Riegel, 522 U.S. at 323 (quoting Lohr, 518 U.S. at 493). The contractual obligation to honor an express warranty included on a pesticide label, for example, "does not require the manufacturer . . . to say anything particular in that warranty," and thus establishes no requirement. Bates, 544 U.S. at 445. But in approving applications for a new or amended pesticide registration, the EPA substantively restricts what precautionary statements may appear on a pesticide's label, and the Preapproval Regulation thereby requires labels

to take a particular form consistent with those substantive restrictions. By virtue of the Preapproval Regulation, the EPA's approval determinations impose "requirements" as that term is employed in section 136v(b).[14]

C. Applying the Parallel-Requirements Test

As we have explained, the Supreme Court in Bates held that lower courts should apply section 136v(b) using the parallel-requirements test, identifying the relevant state and

[14] The Court of Appeals for the Eleventh Circuit distinguished FIFRA from the MDA in the course of holding that the EPA's preapproval determinations do not establish any requirement for the purposes of preemption under section 136v(b). Carson IV, 92 F.4th at 994-95. But in its analysis of "[t]he statutes' distinct approval processes," id. at 995, we believe the court overlooked a crucial similarity between the two regulatory schemes. Although it recognized that a pesticide's label may not be modified once the EPA has approved it, see id. at 990, its discussion of the differences between each statute's approval processes did not consider the similarity between that prohibition and the analogous one established under the MDA, see id. at 994-95. And because that prohibition under the MDA was central to the Supreme Court's explanation for why premarket approval does impose requirements for the purposes of preemption, see Riegel, 552 U.S. at 323 ("[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application . . . ."), the existence of an analogous prohibition under FIFRA strikes us as a crucial similarity that outweighs the differences between FIFRA and the MDA cited in Carson IV.

federal labeling requirements then comparing the two to determine whether they are equivalent. But our analysis of FIFRA and its implementing regulations has revealed that FIFRA's labeling requirements are articulated at two distinct levels of generality. On the one hand, under the broad statutory definition of misbranding, a pesticide is misbranded simply if its label omits a warning necessary for safe use; no specifically identified warning is required to be included or omitted. See 7 U.S.C. § 136(q)(1)(G). The Schaffners apply the parallel-requirements test using a Federal Comparator that incorporates this standard alone, directly comparing the Pa. Duty to Warn with the statutory definition of misbranding. Schaffner Br. 29-30. So did the Courts of Appeals for the Ninth and Eleventh Circuits in holding that section 136v(b) does not preempt duties to warn imposed by California and Georgia law.[15] See Carson IV, 92 F.4th at 991-92; Hardeman II, 997 F.3d at 955-56. On the other hand, the Preapproval Regulation requires pesticide labels to contain certain specific contents, including the precautionary statements contained on the pesticide's Preapproved Label. Monsanto applies the parallel-requirements test using a Federal Comparator that incorporates this specific regulatory requirement, not just the broad statutory misbranding standard. Monsanto Br. 30.

[15] While the Court of Appeals for the Eleventh Circuit appeared to recognize that the Preapproval Regulation generally prohibits modifications to pesticide labels absent an application for amended registration, Carson IV, 92 F.4th at 990, it considered only the statutory definition of misbranding when applying the parallel-requirements test, giving no explanation for that choice, id. at 991-92.

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 we must employ when applying the parallel-requirements test in this case. Should we ask whether the Pa. 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?

We hold 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. If EPA regulations specifically identify the contents required to be included on a pesticide label, a state-law requirement is preempted unless it is equivalent to that specific regulatory requirement. The state-law duty cannot survive preemption simply because its standard of liability is equivalent to the broad statutory definition of misbranding. We therefore apply the parallel-requirements test in this case by comparing the Pa. Duty to Warn with a Federal Comparator that incorporates the Preapproval Regulation.

The principal holding articulated in Bates was that the parallel-requirements test governs preemption under section 136v(b). The Supreme Court did not itself apply that test to the plaintiffs' claims, but rather remanded for the Court of

Appeals to do so. Bates, 544 U.S. at 452-53. Nonetheless, the Court provided guidance concerning how the parallel-requirements test was to be applied on remand. After explaining that "a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption," id. at 453, the Court provided two illustrations of state failure-to-warn claims that would not be equivalent to the relevant Federal Comparator and would therefore be preempted. One example involved a "failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION.'" Id. In order to apply the parallel-requirements test to such a claim, the Court explained, "[s]tate-law requirements must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." Id. A state-law requirement to employ 'DANGER' on a pesticide label would thus be preempted were it "inconsistent with 40 CFR § 156.64 (2004), which specifically assigns ['DANGER' and 'CAUTION'] to particular classes of pesticides based on their toxicity." Id.

The Court's analysis of section 156.64 in Bates indicates that the parallel-requirements test should be applied using more specific EPA regulations requiring pesticide labels to bear particular contents, where such regulations exist, rather than using the broad statutory definition of misbranding. Under the latter approach, which the Schaffners adopt, alleged liability under state law for using 'CAUTION' on a pesticide label would not be preempted so long as the label satisfies the statutory definition of misbranding by omitting "a warning . . . which may be necessary and if complied with . . . is adequate

to protect health and the environment."[16] 7 U.S.C. § 136(q)(1)(G). But when the Court analyzed this example in Bates, it did not consider or even mention the statutory definition of misbranding. See 544 U.S. at 453. Instead, it compared the state-law duty with only the specific regulatory requirement to include certain identified contents on the pesticide label. Id. And it explained that the hypothetical state-law duty was preempted simply because it was not equivalent to the federal regulatory requirement: "a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would

[16] Indeed, a plaintiff bringing the hypothetical claim discussed in Bates almost surely could allege that the label violated not only state law but also the federal prohibition on misbranding, as that term is defined in FIFRA. A plaintiff who sues to recover damages for any alleged failure to warn, such as for the use of "CAUTION" rather than "DANGER" on a pesticide label, must allege that the label's inadequate warnings caused her to be injured. Crediting those allegations, the pesticide's label would likely satisfy the statutory definition of misbranding: if the use of "CAUTION" caused the plaintiff's injuries, then a warning using "DANGER" (or some other signal word) instead was "necessary . . . to protect health." 7 U.S.C. § 136(q)(1)(G). The same facts establishing the defendant's liability for the failure to warn would also establish that the pesticide violated the statutory prohibition on misbranding. If the parallel-requirements test were applied using the statutory definition, as the Schaffners urge, then there would be no preemption in these circumstances, despite the Court's unambiguous conclusion to the contrary. The hypothetical thus weighs against our adopting the Schaffners' approach.

be pre-empted because it is inconsistent with 40 CFR § 156.64 (2004), which specifically assigns these warnings to particular classes of pesticides based on their toxicity." Id. This discussion indicates that a state-law duty is preempted if "relevant EPA regulations that give content to FIFRA's misbranding standards," id., would prohibit adding the warning that state law requires. If so, any equivalence between the state-law duty and the statutory definition of misbranding does not prevent the preemption of state law.

Like the regulation the Court discussed in Bates, which requires specific signal words such as "CAUTION" or "DANGER" to appear on labels for different types of pesticides, see 40 C.F.R. § 156.64, the Preapproval Regulation also gives content to FIFRA's misbranding standards. Section 156.64 does not explicitly define "misbranded," a word that it does not even use. See id. Instead, it gives content to the misbranding standard by prohibiting one type of label that the EPA believes would constitute misbranding — namely, labels that do not bear the requisite signal words. The Preapproval Regulation gives content to FIFRA's misbranding standards in the same sense. Because the EPA approves a pesticide label only if it "has determined that the product is not misbranded as that term is defined in FIFRA," 40 C.F.R. § 152.112(f), the requirement not to modify the Preapproved Label likewise prohibits pesticides from bearing particular labels that, in the EPA's view, constitute misbranding. Each regulation requires pesticide labels to conform to the EPA's opinion as to whether specific labels would constitute misbranding, and thus each "give[s] content to" the broad requirement that such labels not be misbranded. Bates, 544 U.S. at 453.

The Court explained in Bates that whether a state-law duty allegedly requiring the use of 'DANGER' rather than 'CAUTION' would be preempted depends on a comparison between that duty and the regulation requiring that 'CAUTION' be used, regardless of whether the plaintiff plausibly alleges the label to satisfy the statutory definition of misbranding. Id. So too, whether the Pa. Duty to Warn is preempted depends on a comparison between it and the Preapproval Regulation, regardless of whether the label is alleged to satisfy the statutory definition of misbranding. Because the Preapproval Regulation gives content to FIFRA's prohibition on misbranding, Bates requires us to incorporate that regulation into the Federal Comparator when applying the parallel-requirements test here. See id. at 454 (Breyer, J., concurring) (emphasizing "the practical importance of the Court's statement that state-law requirements must 'be measured against' relevant Environmental Protection Agency (EPA) regulations 'that give content to [FIFRA's] misbranding standards'" (quoting id. at 453)).

Even were we not bound by Bates, section 136v(b) itself indicates that the parallel-requirements test should be applied by comparing state-law requirements to a Federal Comparator that incorporates content-giving regulations rather than to one based solely upon the broad statutory definition of misbranding. The Supreme Court has "oft-repeated" its comment that "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." Lohr, 518 U.S. at 485 (alteration in original) (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)). Thus, our "understanding of the scope of a pre-emption statute," such as section 136v(b), "must rest primarily on a fair understanding of *congressional purpose*." Id. at 485-86 (quotation marks omitted). We draw

that understanding of congressional purpose primarily from the text of the statute and from its surrounding framework. Id. at 486

Here, Congress has made the purpose of section 136v(b) transparent by titling it "Uniformity." 7 U.S.C. § 136v(b); see Merit Mgmt. Grp., LP v. FTI Consulting, Inc., 583 U.S. 366, 380 (2018) (explaining that "section headings . . . supply cues as to what Congress intended" (quotation marks omitted)). Congress enacted section 136v(b) to ensure that pesticide labeling requirements would be uniform across the nation. Accord Schoenhofer v. McClaskey, 861 F.3d 1170, 1174 (10th Cir. 2017) ("For labeling . . . the statute requires national uniformity."). We must interpret that provision to realize the purpose that animates it while remaining consistent with its text. See Merit Mgmt. Grp., 538 U.S. at 380 ("[S]ection headings cannot limit the plan meaning of a statutory text . . . .").

The level of generality at which a rule is framed often affects the degree of uniformity in how it will be applied on different occasions. Different interpreters may apply a vague, broad rule differently given the same facts, while they are likely to apply a specific, precise rule more consistently. Because misbranding is defined by statute as the omission of warnings "necessary . . . to protect health," 7 U.S.C. § 136(q)(1)(G), that standard cannot be applied without determining which warnings are in fact necessary to protect health, a challenging question about which reasonable individuals may disagree. This very case provides a suggestive illustration, as disagreement has persisted for decades over whether the Cancer Warning is necessary to protect Roundup users' health. By contrast, the Preapproval Regulation may be

applied by comparing the label a pesticide actually bears with its Preapproved Label, a straightforward matter about which disagreement is unlikely. The broad statutory definition of misbranding is likely to be applied less uniformly in practice than a regulatory requirement to include specific contents on pesticide labels.

The parallel-requirements test affects the uniformity of state-law labeling requirements by determining which state-law duties FIFRA preempts. If state-law duties to warn can survive preemption so long as they are equivalent to the broad statutory definition of misbranding, then FIFRA would not preempt state-law duties to warn that simply require the inclusion of all warnings necessary to protect health. State-law duties framed in these vague and broad terms would produce considerable heterogeneity, not uniformity, in the labels that pesticides are required to bear, for different factfinders deciding different individual cases might reasonably disagree about whether a particular warning was necessary to protect health. But if the parallel-requirements test were applied to preempt any state-law duty that is not equivalent to EPA regulations requiring pesticide labels to bear certain specific contents, then state-law duties to warn would likely be considerably more uniform, for different factfinders are unlikely to disagree about whether a pesticide label bears the specific contents required by regulation.

Congress's aim of instituting uniform rules for pesticide labeling would thus be realized more effectively were state-law requirements "measured against any relevant EPA regulations that give content to FIFRA's misbranding standards," Bates, 544 U.S. at 453, rather than against the statutory definition of misbranding itself. Where no such regulations exist, of course

the parallel-requirements test can only be applied using the statutory definition, despite any consequent risk of heterogeneous state-law labeling requirements. But the Preapproval Regulation gives content to the broad misbranding standard by specifically requiring a pesticide's label to bear the particular precautionary statements on its Preapproved Label. We therefore apply the parallel-requirements test using a Federal Comparator that incorporates that specific regulatory requirement.

* * * * *

The parties reach different conclusions as to whether section 136v(b) preempts the Pa. Duty to Warn because they identify the Federal Comparator differently in applying the parallel-requirements test. We have concluded that the test must be applied by comparing the Pa. Duty to Warn with a Federal Comparator that incorporates the Preapproval Regulation. That question having been resolved, only the straightforward task of making the comparison remains. Monsanto's omission of the Cancer Warning from the Roundup label allegedly violated the Pa. Duty to Warn. But it did not breach the Preapproval Regulation — and thus the Federal Comparator — because Roundup's Preapproved Label omitted the Cancer Warning. As Monsanto's alleged violation of the Pa. 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, and the Schaffners' claim for failure to warn is preempted under section 136v(b).

V. The Schaffners' Counterarguments

The Schaffners' counterarguments ultimately fail to persuade us of their claim that the Pa. Duty to Warn cannot be preempted by virtue of the omission of the Cancer Warning from Roundup's Preapproved Label.

A. Indian Brand Farms

The Schaffners first cite the discussion of Bates found in Indian Brand Farms, Inc. v. Novartis Crop Protection Inc., 617 F.3d 207 (3d Cir. 2010), one of our few precedents addressing preemption under FIFRA. The pesticide label alleged in Bates to violate state law conformed to that pesticide's Preapproved Label. See Bates, 544 U.S. at 434-35. When interpreting Bates in Indian Brand Farms, therefore, we commented that the Supreme Court's decision to remand that case to the Court of Appeals rather than to reverse "established that mere inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration did not necessarily mean that the state law duty was preempted." Indian Brand Farms, 617 F.3d at 222. Citing that statement, the Schaffners argue that a state-law duty cannot be preempted simply because it requires a warning that was not included on a pesticide's Preapproved Label. Schaffner Br. 33.

Our comment in Indian Brand Farms is consistent with our holding today and with the reasoning that supports it. As we explained in Indian Brand Farms, the fact that a pesticide's Preapproved Label differs from the label allegedly required by state law "[does] not necessarily mean that the state law duty was preempted." Id. (emphasis added). As a result, state law

may, in some circumstances, require a pesticide's label to bear particular contents that were excluded from its Preapproved Label. Our reasoning in this opinion fully respects that principle. We do not hold that FIFRA necessarily preempts any state-law duty requiring modification to a pesticide's Preapproved Label. Rather, we hold only that such duties may sometimes be preempted, including in the circumstances of this case.

First, given the Supreme Court's explicit explanation in Bates for its choice to vacate rather than reverse, we read that disposition — and our commentary on it in Indian Brand Farms — to address only the preemptive effect of 7 U.S.C. § 136v(b) when considered on its own. By contrast, our holding today that the Pa. Duty to Warn is preempted rests not on that section alone but rather on its effect when considered jointly with the Preapproval Regulation, which was not examined in Bates. As discussed, the primary question addressed in Bates was only whether the parallel-requirements test governs the preemption of state law under section 136v(b). See Bates, 544 U.S. at 436-37. In its briefing, the respondent "chose[] to mount a broader attack on the 'parallel requirements' interpretation" of section 136v(b). Id. at 453 n.27. And while the Court "settled on [its] interpretation of" that provision, it declined to decide the remaining question of "whether that provision pre-empts petitioners' . . . failure-to-warn claims." Id. at 453. The parties debated — and the Court decided — what standard governs whether a state requirement is preempted under section 136v(b) without further applying that standard to the state-law duty allegedly violated in Bates. And the Court vacated the decision below rather than reversing it so that the respondent could "address these matters on remand." Id.

The Court's choice to vacate rather than reverse in Bates plausibly indicates that section 136v(b) does not on its own preempt all state-law duties to include a warning that was omitted from a pesticide's Preapproved Label. But the Court expressly did not consider whether state law would be preempted under section 136v(b) in light of requirements imposed through EPA regulation: it "ha[d] not received sufficient briefing on this issue" because the parties had not "identified any EPA regulations that further refine [FIFRA's] general [misbranding] standards in any way that is relevant to petitioners' allegations." Id. at 453 & n.27. Because the Court did not analyze the preemptive effects of EPA regulations under section 136v(b), we do not understand its disposition of Bates to express any view on what those effects are. While the remand may be relevant to our interpretation of section 136v(b), it does not constrain our analysis of whether state-law duties are preempted by EPA regulations, such as the Preapproval Regulation, that were expressly not considered in Bates. The remand in Bates therefore does not undermine our conclusion in this opinion that FIFRA preempts the Pa. Duty to Warn in light of the Preapproval Regulation.

In turn, our discussion of Bates in Indian Brand Farms was consistent with the Court's express explanation for its disposition in Bates. The discrepancy between a pesticide's Preapproved Label and the label allegedly required by state law does not "necessarily" result in the state law's being preempted, as we explained in Indian Brand Farms, see 617 F.3d at 222, in that section 136v(b) does not of its own force preempt all such state-law duties. Instead, to quote the very next sentence of our opinion in Indian Brand Farms, "[w]e must look to the *requirements* imposed by FIFRA." Id. And, of course, those requirements may depend on the regulations

the EPA has promulgated: whether FIFRA preempts state-law duties to modify a pesticide's Preapproved Label will depend on whether those state-law requirements are in addition to or different from the content-giving regulatory requirements that the EPA has promulgated. By noting that FIFRA does not "necessarily" preempt state-law duties requiring modification to a pesticide's Preapproved Label, our opinion in Indian Brand Farms merely recognized the possibility that such duties would not be preempted — a possibility that may or may not be realized depending on what regulations the EPA enacts. Our FIFRA preemption analysis in this case thus is consistent with Indian Brand Farms, as it rests specifically on the Preapproval Regulation. We do not take section 136v(b) automatically to preempt any state-law duty that would require modification of a pesticide's Preapproved Label, regardless of what regulatory requirements actually have been imposed under FIFRA.

Furthermore, our holding today would be consistent with our comment in Indian Brand Farms even were we to interpret it as addressing the preemptive effect of the regulations promulgated pursuant to FIFRA, not just of section 136v(b) on its own. We do not today endorse the claim, rejected in Indian Brand Farms, that any state-law duty requiring modification of a pesticide's Preapproved Label is preempted. See 617 F.3d at 222. The Pa. Duty to Warn, we have held, is preempted by virtue of the Preapproval Regulation. And the Preapproval Regulation does not prohibit all modifications to a pesticide's Preapproved Label; rather, as discussed above, it carves out an exception for modifications by notification (and without notification) authorized under 40 C.F.R. § 152.46. See 40 C.F.R. § 152.44(a). There is consequently no per se requirement under FIFRA that a pesticide's label conform to its Preapproved Label with respect

to the label contents that may be modified by notification or without notification. See generally PRN 98-10. And absent such a regulatory requirement, no federal requirement would necessarily preempt a state-law duty requiring a modification to those contents on the Preapproved Label. With respect to such duties, "inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration [would] not necessarily mean that the state law duty was preempted," just as we explained in Indian Brand Farms. 617 F.3d at 222.

We do not hold the Schaffners' claim for failure to warn to be preempted on the grounds, properly rejected in Indian Brand Farms, that any such claim is "necessarily" preempted if it would require a modification to the pesticide's Preapproved Label. Rather, as we explained in Indian Brand Farms, when applying section 136v(b) "[w]e must look to the *requirements* imposed by FIFRA." 617 F.3d at 222. The opinion in Indian Brand Farms thus continues its analysis by examining the text of the statute and of applicable agency actions in order to identify the relevant requirements, just as we have done here. We conclude that the Schaffners' claim is preempted because of the specific requirement imposed through the Preapproval Regulation, which prohibits the modification of a pesticide's Preapproved Label without further approval unless the exception for modification by notification (or without notification) applies.

B. 7 U.S.C. § 136a(f)(2)

The Schaffners next claim that FIFRA itself does not allow the EPA's registration of a pesticide to affect the

preemption of state-law duties under that statute. Under FIFRA,

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

7 U.S.C. § 136a(f)(2). The Schaffners contend that Monsanto's preemption argument in essence raises registration as a defense to misbranding, as Monsanto cites the omission of the Cancer Warning from Roundup's Preapproved Label as a basis for denying that it has violated any requirement imposed under FIFRA. Schaffner Br. 32-33. Because section 136a(f)(2) makes clear that a pesticide may be misbranded even if it is registered, the Schaffners conclude that the Federal Comparator must incorporate only the broad statutory definition of misbranding, not the determinations made by the EPA during the registration process. Id. 32-34, 37-39. The Courts of Appeals for the Ninth and Eleventh Circuits each agreed, citing this provision as one basis for their holdings that FIFRA does not preempt similar state-law failure-to-warn claims. See Carson IV, 92 F.4th at 993; Hardeman II, 997 F.3d at 956.

We agree with the Schaffners that EPA registration cannot be "dispositive of FIFRA compliance." Schaffner Br. 33. Because section 136a(f)(2) provides that registration cannot constitute a defense to a violation of FIFRA, a pesticide

otherwise liable for violating FIFRA cannot defeat liability simply because it is registered.[17] We therefore cannot interpret any regulation promulgated under FIFRA to implement a rule under which the mere fact of registration would entail, dispositively, that a pesticide was not misbranded. But we have adopted no such interpretation in this opinion. We have instead

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[17] This provision predates the modern system of pesticide registration under FIFRA and is instead a vestige of an earlier system, enacted in 1947, that mandated pesticides be registered even if the government deemed their labels non-compliant with FIFRA. See Federal Insecticide, Fungicide, and Rodenticide Act § 4(c), Pub. L. No. 80-104, 61 Stat. 163, 168 (1947) ("If . . . the registrant insists that such corrections [to the label] are not necessary and requests in writing that [the article] be registered, the Secretary shall register the article . . . . In no event shall registration of an article . . . be construed as a defense for the commission of any offense prohibited under . . . this Act." (emphasis added)). Congress later amended FIFRA to prohibit the registration of pesticides with non-compliant labels while retaining the provision that registration was not a defense to FIFRA violations, perhaps to address non-compliant products already on the market. See Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1964 § 3, Pub. L. No. 88-305, 78 Stat. 190, 190, 192 ("If . . . the applicant for registration does not make the corrections [to the label], the Secretary shall refuse to register the article . . . . In no event shall registration of an article be construed as a defense for commission of any offense prohibited . . . under this Act." (emphasis added)). Given the passage of time and the introduction of re-registration requirements, see, e.g., 7 U.S.C. §§ 136a(g), 136a-1(a), this provision may have simply lost some vitality.

concluded that under the Preapproval Regulation the EPA's approval of a proposed label "give[s] content to FIFRA's misbranding standards," Bates, 544 U.S. at 453, as the pesticide's label must conform to its Preapproved Label with respect to precautionary statements. A pesticide can still be misbranded despite being registered.[18] The EPA's registration of a pesticide is therefore not dispositive as to whether it is misbranded, as section 136a(f)(2) would forbid. Rather, registration affects the content of the requirements imposed under FIFRA, as registration determines what label the pesticide must bear (at least in certain respects). And while section 136a(f)(2) indicates that registration cannot itself be a defense to a charge of misbranding, we do not understand it to indicate that the registration process cannot play any role in determining the content of a requirement imposed under FIFRA, the only role we have assigned it in this opinion.

C. Mead and the Force of Law

The Schaffners' final argument begins with the claim that only EPA actions with the "force of law" may exert preemptive force under section 136v(b) by giving content to a Federal Comparator used in applying the parallel-requirements test. Schaffner Br. 37, 39. Relying on the Supreme Court's analysis of the "force of law" in United States v. Mead Corp.,

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[18] Most obviously, a registered pesticide may be misbranded if it bears a label that differs from its Preapproved Label. And we have explicitly left unresolved how FIFRA would apply following the discovery of information rendering a pesticide's Preapproved Label inaccurate were the use of that label continued without applying for amended registration or otherwise notifying the EPA. See supra note 13.

533 U.S. 218, 229-30 (2001),[19] they then conclude — as did our colleagues on the Courts of Appeals for the Ninth and Eleventh Circuits — that because the EPA actions Monsanto relies upon in its preemption arguments lacked the force of law, they cannot affect the content of the Federal Comparator we must compare to the Pa. Duty to Warn. Schaffner Br. 35-37, 39; Carson IV, 92 F.4th at 993; Carson II, 51 F.4th at 1362-65; Hardeman II, 997 F.3d at 956-57.

In Carson II and Hardeman II, the key premise in these arguments — that section 136v(b) bestows preemptive force only on agency action with the force of law, as that concept is understood in Mead — was supported only with a citation to the Supreme Court's decision in Wyeth v. Levine, 555 U.S. 555 (2009). See Carson II, 51 F.4th at 1362 (citing Wyeth, 555 U.S. at 576, 580); Hardeman II, 997 F.3d at 957 (citing Wyeth, 555 U.S. at 576, 580); see also Schaffner Br. 32 (quoting Hardeman II, 997 F.3d at 956). The opinion in Wyeth, however, did not interpret a statutory provision that expressly preempted state law, as section 136v(b) does. Instead, it addressed the distinct doctrine of implied preemption, under which state law is preempted if it either conflicts directly with federal law or poses an obstacle to achieving the aims of federal law. Wyeth, 555 U.S. at 563-64. For that reason, the Court of Appeals for the Eleventh Circuit, sitting en banc, vacated Carson II's holding that agency action must possess the force of law to

[19] The Court in Mead employed the notion of the "force of law" in order to identify the appropriate scope of Chevron deference. 533 U.S. at 231-34. Because the Supreme Court has since overruled Chevron, see Loper Bright, 144 S. Ct. at 2273, the reliance on Mead in Hardeman II and Carson II might no longer be appropriate today.

preempt state law pursuant to an express preemption provision. Carson III, 74 F.4th at 1267-68. Instead, when Congress has expressly authorized the preemption of state law by statute, "the meaning of the express-preemption provision . . . triggers preemption." Id. at 1268. Thus, "[o]ur role when confronted with an express-preemption provision is to apply the text that embodies Congress's decision." Id. We have already concluded that the Preapproval Regulation establishes a "requirement" under FIFRA's express preemption provision, 7 U.S.C. § 136v(b).[20] See supra Part IV(B). And as Congress

[20] On remand following Carson III's vacatur of Carson II, the Court of Appeals for the Eleventh Circuit held that agency action constitutes a "requirement" for the purposes of section 136v(b) only if it possesses the force of law, as that concept is used in Mead. Carson IV, 92 F.4th at 992-93. It then declined to "conflate FIFRA's broad prohibition on misbranding—indisputably a 'requirement'—or even generally applicable agency regulations, with an individualized finding that a particular pesticide is not misbranded," concluding that the EPA's registration of a pesticide lacks the force of law and cannot preempt state law. Id. at 993. But while a "finding that a particular pesticide is not misbranded," id., may not constitute a requirement for the purpose of section 136v(b), the EPA has done more than merely issuing such a finding. As the court itself recognized in Carson IV, the Preapproval Regulation prohibits the modification of a pesticide's Preapproved Label. See id. at 990; see also 42 C.F.R. § 152.44(a). In Carson IV, the court did not consider the Preapproval Regulation before concluding that the EPA's actions with respect to Roundup lacked the force of law and therefore established no "requirement" for the purposes of section 136v(b). 92 F.4th at 992-95. We have explained,

has decreed in the text of that provision that federal "requirements" have preemptive force, see id., no further analysis is necessary.

VI. Conclusion

We conclude that neither issue preclusion nor administrative law provides a basis upon which to affirm the MDL Court's ruling that the Schaffners' failure-to-warn claim is not preempted under FIFRA. As to issue preclusion, we adopt section 29(7) of the Second Restatement. A court has discretion to decline to apply issue preclusion if the "issue is one of law and treating it as conclusively determined would inappropriately foreclose opportunity for obtaining reconsideration of the legal rule upon which it was based." Restatement (Second) of Judgments § 29(7) (Am. L. Inst. 1982). For that reason, we do not apply issue preclusion in this case. The complex subject of preemption under FIFRA has not been comprehensively analyzed in prior caselaw, and the Supreme Court has yet to address FIFRA preemption in the specific circumstances presented by this case. Independently evaluating the merits of Monsanto's preemption arguments therefore advances our "function of developing the law." Id. cmt. i.

As to those preemption arguments, our analysis differs from that of the MDL Court — and of our colleagues in other

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however, that in our view the Preapproval Regulation does impose a "requirement." See supra Part IV(B). As a legislative rule promulgated following notice and comment, it is "a rule of law that must be obeyed." Bates, 544 U.S. at 445.

courts who have agreed with its conclusion — chiefly in how we define the Federal Comparator that must be employed in applying the parallel-requirements test. We hold that the Preapproval Regulation prohibits modifying the health warnings on a pesticide's Preapproved Label, including by adding the Cancer Warning; that this prohibition constitutes a "requirement" for the purposes of section 136v(b); and that when we apply the parallel-requirements test the Federal Comparator must incorporate this regulatory requirement rather than incorporating only the statutory definition of misbranding. This approach best achieves Congress's stated aim of uniformity in pesticide labeling. And the parallel-requirements test is not satisfied when the Pa. Duty to Warn and the Federal Comparator are compared under this approach: they are not equivalent because Monsanto's alleged violation of the Pa. Duty to Warn does not constitute a violation of the Preapproval Regulation. We thus conclude that the Schaffners' failure-to-warn claim is preempted under section 136v(b).

For these reasons, we will reverse the judgment of the District Court.