No. 03-388

IN THE
Supreme Court of the United States

DENNIS BATES, ET AL.,
Petitioners,
v.

DOW AGROSCIENCES LLC,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR PETITIONERS

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QUESTION PRESENTED

Which, if any, state-law crop damage claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*

PARTIES TO THE PROCEEDING

Plaintiff-Appellee in the proceedings below was Dow AgroSciences LLC.

Defendants-Appellants in the proceedings below were Dennis Bates; Jimmy Burson; Benny Judah d/b/a Clearwater Farms; Tommy Coleman; Richard Cox; Wayne Davis; Neil Friessen; Jake Forese; Thomas Fuston; Arthur Galvan d/b/a G-5 Partnership; Greg Hughes; Sandra and Karl Don Hughes d/b/a JH Cattle Co.; Rudy Klassen; Ronnie Love; Kevin Mathis; Brad Palmer; Kirk Parrish d/b/a K-L Farms; Jerry Parrish; Joevelyn Patterson; Donald Gruben; Stacey Price; Benny Judah d/b/a Progressive Farms; Morris Rushing d/b/a Pea-Cot Farms; Billy Shannon; Floyd Stokes; Craig West; and Frenchie Lee Wheeler.

Burk Denman was a Defendant in the district court proceedings but was dismissed as an Appellant in the court of appeals proceedings.

STATEMENT PURSUANT TO RULE 29.6

None of the corporate Petitioners has a parent company, and no publicly held company owns 10% or more of the stock of any such corporate Petitioner.

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JURISDICTION

The court of appeals entered judgment on June 11, 2003. The petition for a writ of certiorari was filed on September 9, 2003, and granted on June 28, 2004 (124 S. Ct. 2903). Jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS

Relevant provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*, and of Title 40 of the Code of Federal Regulations are reproduced in an addendum to this brief.

STATEMENT

Petitioners are a group of Texas farmers who seek recovery under state law for the substantial crop damage caused by a pesticide, Strongarm, in the growing season immediately after the Environmental Protection Agency ("EPA") approved it. They asserted the same types of claims that have been made against pesticide manufacturers for nearly a century – strict liability in tort, breach of warranty, breach of contract, negligence, fraud, and deceptive trade practices. Those claims arose out of the respondent manufacturer's written representations on the pesticide's label, and oral representations made in face-to-face meetings with the farmers before and after they purchased and applied Strongarm to the soil. In holding all of those claims preempted, the court below gave sweeping effect to the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b). The court opined that any state-law liability that might "induce" the manufacturer to change its label was "express[ly]" preempted under § 136v(b). Pet. App. 20a.

That holding affords pesticide manufacturers *carte blanche* to determine the scope of preemption because they – and not federal regulators – decide what to put on the

label. The notion that manufacturers have the authority to preempt claims that seek to redress injuries they cause, however, is alien to this Court's approach to preemption analysis, Congress's purposes in enacting FIFRA, historical practice throughout the twentieth century, and common sense. In legislation that sought to address the potential horrors of an unregulated pesticide industry, it is unthinkable that Congress – without debate – intended to exonerate manufacturers from traditional state-law remedies for the injuries they cause from dangerous chemicals.

1. Beginning in the late nineteenth century, farmers in the United States began to use a variety of primitive chemicals to attack insect pests, such as Paris green (a concoction of copper and arsenic), calcium arsenate, nicotine sulfate, and sulfur. *See* J. Whorton, *Before Silent Spring* 20-21 (1974). Those primitive chemicals augured significant changes in the agricultural pesticide industry, which grew dramatically after World War II, when advances in chemistry occasioned by military needs led to the introduction of DDT and BHC, among others. *See*, *e.g.*, *id.* at 248-50; *Report of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health* 44-46 (U.S. Dep't HEW 1969) ("*HEW Report*"). The seeming euphoria over the benefits of pesticides in general, and DDT in particular, led to a 1944 Nobel Prize award to the inventor of DDT. But by the 1960s, following publication in 1962 of Rachel Carson's *Silent Spring*, a major reassessment began of pesticides, due to the human health risks and environmental hazards caused by DDT. *See generally* H. Wellford, *Sowing the Wind* (1972); F. Graham, *Since Silent Spring* (1970); R. Rudd, *Pesticides and the Living Landscape* (1964). In 1972, EPA cancelled the registration of DDT in the United States. By 2001, 92 nations (including the U.S.) had signed a treaty pledging to phase out persistent organic pollutants, including DDT. *See* Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 40 I.L.M. 532, *at* http://www.pops.int/.

Notwithstanding the disastrous experience with DDT, pesticide use on farms rose rapidly in the 1960s, from $440 million in sales in 1964 to $12 billion in 1969. *HEW Report* at 46. Some 900 active pesticidal chemicals formulated into more than 60,000 preparations were marketed by that time. *Id.* By 1976, pesticides were used on 70% of U.S farm acreage planted, up from 50% five years before. *See* George Getschow, *Farmers Using More and More Pesticides To Safeguard Investment as Well as Crops*, Wall St. J., June 14, 1976, at 24.

2. The introduction of pesticides early in the twentieth century, and the attendant problems they created, led Congress to enact the Insecticide Act of 1910. That Act was principally a labeling measure covering insecticides and fungicides, the purpose being to prohibit the manufacture or shipment of misbranded or adulterated products that move in interstate commerce. *Id.* §§ 1, 2, 36 Stat. 331. Although the Department of Agriculture ("USDA") was authorized to examine specimens, Congress did not require registration or other government approval of pesticides. *Id.* § 4, 36 Stat. 332. The 1910 Act was silent as to civil remedies for violations, providing only for criminal penalties and civil actions by the federal government. *Id.* §§ 1-2, 10, 36 Stat. 331, 334.

In 1947, Congress enacted FIFRA, which repealed the 1910 Act, *see* § 16, 61 Stat. 172. FIFRA provided that an "economic poison" – otherwise defined as a chemical pesticide – had to be registered before being marketed in interstate commerce. *Id.* § 4(a), 61 Stat. 167. "Like its 1910 predecessor, the principal thrust of the 1947 FIFRA was to protect consumers on the farm and in the orchard from ineffective products." 3 W. Rodgers, Jr., *Environmental Law: Pesticides and Toxic Substances* § 5.3, at 34 (1988).

By the end of the 1960s, however, it was clear that the existing system of federal pesticide regulation was inadequate. A House subcommittee investigation in 1969 chronicled a plethora of problems, including approvals of pesticides without compliance with federal procedures,

approvals of labels that failed to warn users of possible hazards, and actions to cancel dangerous pesticides that were substantially delayed. *See* H.R. Rep. No. 91-637 (1969); *see also* Rodgers § 5.2, at 31.

Notwithstanding enactment of the 1910 or 1947 Acts, including the requirement that pesticides be federally registered before entering interstate commerce, from the earliest uses of agricultural chemicals, farmers commonly pursued claims for compensation under common law and state statutes for injuries caused by pesticides. For example, claims against pesticide manufacturers alleged crop damage for failure to test a product before it was released into the market.[1] Indeed, state courts imposed on manufacturers a duty to test their products for safety and effectiveness "under the existing climactic and soil conditions" of each State in which they sold the product. *Ebers v. General Chem. Co.*, 17 N.W.2d 176, 181 (Mich. 1945) ("[D]efendant cannot escape liability merely by showing that it followed the recommendations of [USDA] . . . based upon field tests in States *other* than Michigan.") (emphasis added). Likewise, courts upheld farmers' crop damage claims sounding in negligence under a duty to warn theory.[2] And courts routinely recognized claims against pesticide manufacturers for personal injuries.[3]

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[1] *See, e.g.*, *Chapman Chem. Co. v. Taylor*, 222 S.W.2d 820, 827 (Ark. 1949) (manufacturer "charged with the knowledge which tests would have revealed"); *Henderson v. Cominco Am., Inc.*, 518 P.2d 873, 879, 882-83 (Idaho 1973) (recognizing claim for "failing to test the product").

[2] *See, e.g.*, *Golden Gate Hop Ranch, Inc. v. Velsicol Chem. Corp.*, 403 P.2d 351, 355 (Wash. 1965) ("[I]f [the manufacturer] knew or should have known that the product was dangerous to hops, the appellant was negligent in not advising the respondent of the danger."); *Thompson-Hayward Chem. Co. v. Childress*, 169 So. 2d 305, 312 (Ala. 1964) (recognizing claim for "failure to give notice to or warn plaintiffs of the dangerous nature of [a herbicide]"); *Reasor-Hill Corp. v. Kennedy*, 272 S.W.2d 685, 691 (Ark. 1954) (affirming verdict for failure to warn against crop damage due to insecticide drift).

[3] *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402, 404 (1st Cir. 1965) (upholding verdict on failure-to-warn claims for personal injury;

By the 1960s, the "principles of law which are deducible" from the scores of cases decided throughout the twentieth century involving claims against pesticide manufacturers and sellers led to this statement of settled law: "A duty of due, reasonable care binds [pesticide] manufacturers . . . . This duty of care includes a duty to warn of product-connected dangers, a duty on the part of the manufacturer to subject the product to reasonable tests, and a duty on the part of the seller to subject the product to reasonable inspection." R.D. Hursh, *Liability of manufacturer or seller for injury caused by animal feed or medicines, crop sprays, fertilizers, insecticides, rodenticides, and similar products*, 81 A.L.R.2d 138, 144 (1962) (footnotes omitted).

3. Congressional enactment of the Federal Environmental Pesticide Control Act of 1972 ("1972 Act") amended FIFRA in important ways. *See* § 2, 86 Stat. 973-98, codified at 7 U.S.C. §§ 136 *et seq.*[4] The 1972 Act contained a more detailed registration provision (§ 136a(c) (1976)); added criteria for approval (§ 136a(c)(5)); and imposed consequences of disapproval (§ 136a(c)(6)). 86 Stat. 979-81. Congress augmented the 1970 transfer of authority to administer pesticide registration from USDA to EPA by providing in the 1972 Act for federal authority over the sale and use of pesticides. *E.g.*, § 136j. But the Act also expressly ensured that state and local governments had broad authority to regulate or even ban the sale and use of a federally registered pesticide. § 136v(a). States have the lead in enforcing pesticide use restrictions. § 136w-1.

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finding no FIFRA preemption from label registration, but noting that defendants' compliance with FIFRA labeling requirements was "some evidence that . . . they exercised reasonable care"); *Orr v. Shell Oil Co.*, 177 S.W.2d 608, 614 (Mo. 1943) (affirming verdict against insecticide manufacturer for negligently failing to warn of dangers of human contact with spray ingredients); *West Disinfecting Co. v. Plummer*, 44 App. D.C. 345, 355 (1916) (affirming damages verdict for plaintiff for burn injuries where insecticide manufacturer breached its "duty . . . to label the can containing the fluid so as to show its dangerous character").

[4] Subsequent statutory cites are to Title 7 unless otherwise noted.

As part of the registration process, the manufacturer submits health and environmental data, as well as a draft label. § 136a(c)(1)(C); 40 C.F.R. § 152.50(e). EPA has stressed that "[t]he registrant must take responsibility for quality control of the product's composition and for adequate labeling describing the product, its hazards and uses." 53 Fed. Reg. 15,952, 15,956 (1988). Unlike federal statutes governing tobacco labels, *see* 15 U.S.C. §§ 1333, 4402(a)(1), neither FIFRA nor EPA regulations dictate that any particular language must be used for pesticide labels, except with respect to certain required "signal words" designed to protect human health if the pesticide contains ingredients in three of four toxicity categories. *See* 40 C.F.R. §§ 156.60-156.78.

If a manufacturer meets FIFRA's requirements, then EPA is obliged to register the pesticide. § 136a(c)(5), (7); 40 C.F.R. §§ 152.112, 152.113. Those requirements include: "the name and address of the applicant"; "the name of the pesticide"; "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use"; "the complete formula of the pesticide"; a request as to the product's use (*i.e.*, general or restricted); and, "if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based." § 136a(c)(1)(A)-(F). A "label" is defined as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers," or other detached written matter accompanying the pesticide, such as an instructional booklet, that serves the same purpose as a label. § 136(p)(1), (2)(A). Information required by FIFRA to be on a pesticide's label must be prominently and conspicuously placed in comparison to other labeling information that is not mandated by federal law. § 136(q)(1)(E); 40 C.F.R. § 156.10(a)(2).

Notwithstanding EPA's registration of a pesticide, a label is "misbranded" if it bears false or misleading statements, contains improper directions for use, or displays inadequate cautions or warnings. § 136(q)(1)(A), (F), (G);

see also § 136a(c)(5). Cognizant that, "[f]or liability reasons, companies often voluntarily provide additional information on the label, particularly in the area of precautionary statements," 49 Fed. Reg. 37,960, 37,971 (1984), FIFRA and EPA permit such statements if they do not violate a specific statutory or regulatory requirement, *id.*

4. Although the 1972 Act required EPA to consider data and manufacturer claims concerning the efficacy of a pesticide in determining whether "its composition is such as to warrant the proposed claims for it," § 136a(c)(5)(A) (1976), those burdens were simply too great for the agency. In 1977, EPA Administrator Douglas M. Costle testified, "we feel that far too much Agency time is currently being spent in reviewing efficacy data while shortages abound in the reregistration data validation areas. Since the registrant, the USDA, and pesticide users are generally in a better position to judge efficacy, particularly of agricultural pesticides, we are proposing that the Agency should have explicit authority to waive the efficacy data requirement when appropriate." H.R. Rep. No. 95-343, at 9 (1977). In 1978, Congress acceded to that request by amending the 1972 Act to allow the EPA to waive data requirements "pertaining to efficacy" and to establish a "presumption" in favor of waiver if a pesticide is found to be effective by a state. Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 5, 92 Stat. 819, 825 (§ 136a(c)(5)). EPA then issued a general waiver of its review of label claims concerning pesticide efficacy. *See*, *e.g.*, 44 Fed. Reg. 27,932 (1979). "The assumption in 1978 was that market choices and user votes of confidence were a fair barometer of product workability." Rodgers § 5.3, at 51.

That assumption was confirmed explicitly in 1996, when EPA issued Pesticide Registration Notice 96-4. That notice stated that "it would be incorrect to contend that the label approval process involves an examination of the efficacy of the pesticide." JA 232. EPA noted that the agency, "with Congress' approval, stopped evaluating pesticide efficacy for routine label approvals almost two decades ago.

Further, . . . EPA's regulations do not require a review of efficacy of property damage issues for agricultural pesticides." *Id.* EPA further clarified that the statutory prohibition on "misbranding" "should not be read as reintroducing efficacy concerns into the label approval process." JA 233-34. EPA concluded by stating, "as to pesticide users this Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." JA 235. That guidance – and EPA's 1979 waiver – were in effect when Strongarm was registered.

5. In the early 1990s, the corporate predecessor to respondent Dow AgroSciences LLC ("Dow") began testing and developing a new herbicide that became known as Strongarm.[5] This product was touted as a revolutionary weed control for peanut and soybean crops, because it was designed to be applied once to the soil as a "pre-emergent" prior to the planting of peanut seeds. From then until the peanuts were harvested, the farmer would not need to apply any other herbicide to control noxious weeds that compete with peanuts for important nutrients. The active ingredient in Strongarm, diclosulam, was supposed to attack the roots of "target" weeds, inhibiting their growth, without affecting the "non-target" peanut crop. JA 120. Beginning in the early 1990s, however, Dow scientists learned through field tests that the absorption rate for a herbicide similar to diclosulam was significantly hindered when the soil has a pH level above 7.0. *See* R.G. Lehmann *et al.*, *Degradation of a Sulfonamide Herbicide as a Function of Soil Sorption*, 32 Weed Research 197 (1992) (CA App. 597). Later studies by Dow scientists established that, the higher the soil pH, the less likely diclosulam was

[5] As an appeal from a summary judgment for Dow, the record facts must be construed in the light most favorable to petitioners. *See Wolston v. Reader's Digest Ass'n, Inc.*, 443 U.S. 157, 162 n.5 (1979). Because Dow's motion was based on federal preemption, "no pre-trial discovery was undertaken in this case." Dow Cert. Opp. 3.

to be absorbed in the ground and thus the higher the "effect" of the herbicide on plant life exposed to the chemical. *See* J. Zabik *et al.*, *Terrestrial Field Dissipation of Diclosulam at Four Sites in the United States*, 49 J. Agric. Food Chem. 3284 (2001) (CA App. 590); JA 124. Thus, when soil pH levels reached 7.0 or greater, the Strongarm in the soil would not be readily absorbed and would retard or injure the roots of the non-target peanut plants. JA 126.

Despite those known deficiencies, Dow widely touted the putative benefits of its new pesticide. In 1999, before EPA had registered Strongarm, the Texas Department of Agriculture was sufficiently impressed by Dow's representations that it requested a special exemption to use Strongarm on 184,000 acres, or roughly half of the State's peanut crop. *See* 64 Fed. Reg. 9152, 9152 (1999).[6]

Although EPA declined the State's request, it "conditionally registered" Strongarm on March 8, 2000. JA 63-93. Because peanuts mature on a 150-day growing cycle, seeds in west Texas must be planted on or about May 1 of each year. Dow thus had to act quickly to convey information about Strongarm so that it could be sold for the 2000 planting season. At a series of "Field Days" sponsored by Texas agricultural extension agents employed by Texas A&M University and conducted in 1999 and 2000, Dow agents orally recommended Strongarm to Texas peanut farmers. *See*, *e.g.*, JA 147-48, 152-53, 157-58.

Petitioners, farmers who grow their crop principally for sale as packaged peanuts at baseball games and other sporting events, decided to use Strongarm on the basis of those oral presentations. *See*, *e.g.*, JA 148, 153, 158. It is common in Texas agriculture for farmers to hire their local agricultural supplies outlet or custom chemical applicator to apply the pesticide for them, rather than applying the pesticide themselves. Those applicators, in turn, will mix

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[6] Texas has 320,000-370,000 acres of peanut farmland and ranks second nationally in peanut production. *See* Texas Agric. Ext. Serv., *Texas Peanut Production Guide* 1 (Apr. 2001) ("*Texas Peanut Guide*").

and distribute the pesticide via methods such as sprinkler outlets that they use on the farmers' land or move from farm to farm. In this manner, the farmer contracts out the task of applying pesticides without directly purchasing the pesticide or being aware of the label's contents. In any event, the Strongarm label was in plastic sealing that could not be opened or read until after purchase. *See*, *e.g.*, JA 148.

Within weeks after planting their peanut seeds on or about May 1, the farmers discovered signs of herbicide damage to their crops. Plants "treated with Strongarm were not growing normally, were stunted in their growth, were yellowed and discolored and were not developing foliage." *E.g.*, JA 153, 158; *see* JA 121. At this point, the farmers had applied no chemical to their land other than Strongarm, and they had no reason to suspect that the high pH content of their soil was a factor. JA 153, 158; *see also* JA 125-26, 139, 148, 158.

When the farmers contacted Dow to complain about the effects of Strongarm on their crop and to ask what they should do, Dow officials came to inspect the fields. *See*, *e.g.*, JA 139, 153. Those agents were able to observe a "burning" of the farmers' crop roots and made oral representations as follows: the farmers were advised to "grow out" their crop and keep a record of their extra expenses. *See*, *e.g.*, JA 153, 161-62. Dow would compensate them for those costs, as well as any damages they suffered from using Strongarm. *See*, *e.g.*, JA 148, 162.

By June, the farmers were in a terrible bind. They had little choice at that point but to follow Dow's instructions. The Strongarm was so toxic in their soil that they could not reasonably plow up their peanut plants and plant a different crop, even if their agricultural lenders would have permitted them to do so. But they could tell from the stunted growth of their peanut plants that maturation of the crop would be significantly delayed. Adding to the farmers' difficulties was that Strongarm failed to control noxious weed infestations as promised; the farmers

incurred additional costs in applying other herbicides to combat weeds and additional water to counteract the burning effect of Strongarm.

The resultant stunting of the farmers' crops created special weather-related problems. Most of the affected farms were in west Texas, where autumnal freezing rains make it imperative to harvest the peanuts by approximately October 1 to achieve the best crop. *See Texas Peanut Guide* at 10 (noting that delays in maturation of peanuts "reduce yield and quality and increase the risk of freeze damage and late season drought to peanuts"). Peanuts grow underground and are harvested by tilling up the crops and having them dry above ground. Hot, dry weather is essential to the harvesting process. But, when the stunted plants were not ready to be harvested by October 15, the farmers faced the prospect that, even if their peanuts eventually grew properly to maturity, they would have to harvest them in the fall rainy season, and the crops would be severely damaged or ruined above ground.

In late 2000 – before any new studies could have been completed and before any petitioners had sent demand letters to Dow formally seeking compensation for Strongarm-related injuries – Dow re-registered its Strongarm label with EPA, which approved the amendments on January 30, 2001. JA 123, 181. In that re-registration, Dow altered the label in multiple, significant ways. First, Dow registered a "supplemental" label that was for "distribution and use only in the states of New Mexico, Oklahoma and Texas," JA 179, the three states whose peanut farmers had experienced crop damage from Strongarm in 2000. Second, Dow explicitly stated: "Do not apply Strongarm to soils with a pH of 7.2 or greater." JA 181. (The soil on many petitioners' lands has a pH level of that amount or higher. *See* JA 125.) Third, Dow stated on the new supplemental label that the amount of Strongarm to be applied was .3 to .45 ounces per acre, as opposed to the .45 ounces per acre directed on the label conditionally approved by EPA on March 8, 2000. *Compare* JA 179 *with*

JA 75. Fourth, whereas the original label said nothing about the need for additional applications of herbicides for weed infestations other than nutsedge, *see* JA 87, the supplemental label noted that, "[w]hen using the 0.3-oz rate, weed control results on eclipta, morningglory, nutsedge, and Virginia copperleaf may be variable. A follow up treatment with another herbicide may be necessary for full season control." JA 180. Finally, rather than applying Strongarm prior to planting, the supplemental label stated that the pesticide should be applied *after* planting. JA 176, 180. "Many of the west Texas farms reported peanut injury with preplant incorporation." JA 124.

By the time EPA had conditionally approved Dow's supplemental label for Strongarm in early 2001, the farmers had an idea of the additional expenses and damages they had suffered as a result of the disastrous experiment with Strongarm, although some farmers also discovered that the lingering effects of the Strongarm in their soil impaired their 2001 crops of wheat and cotton (rotated with peanuts for soil regeneration). JA 127. But, when they presented this information to Dow, as its agents had instructed them, Dow refused to pay for the "year 2000 production loss as they promised to do." *E.g.*, JA 139. Beginning in late September 2001, a few petitioners wrote officially to inform Dow of their damages, request payment, and advise that, if no satisfaction was forthcoming, they would file suit in state court to recover their damages. *See*, *e.g.*, JA 36-39. Throughout the autumn, more farmers came forward to advise Dow of the problems they had experienced and to request formally that Dow honor its promise to make whole the farmers who had been damaged by using Strongarm. *See*, *e.g.*, JA 33-34. Under the Texas Deceptive Trade Practices Act ("DTPA"), Tex. Bus. & Com. Code §§ 17.01 *et seq.*, the farmers were required to provide written notification to Dow before they could bring suit in state court. The DTPA provides that no suit filed within 60 days of that notification shall be effective. On December 21, 2001, before the 60 days had expired for the

vast bulk of petitioners, Dow filed suit in federal district court for a declaratory judgment that all of the farmers' claims were preempted by FIFRA. *See* JA 13-23.

6. When Dow sued for declaratory relief, the farmers brought counterclaims asserting various state-law claims, including: strict liability in tort for a defective product; fraud and fraud in the inducement arising out of Dow's knowledge that Strongarm was particularly toxic in high pH soils from prior studies and the post-application representations by Dow officials that they would compensate the farmers for any harm that occurred to their crop from permitting it to grow out; a DTPA claim for deceptive practices in connection with the statements Dow had made to the farmers after Strongarm had been applied to and damaged their crops; estoppel and waiver, on the ground that Dow's contradictory oral off-label representations precluded Dow from relying on its label; negligent misrepresentation; breach of express and implied warranty; negligence; and breach of contract. *See* JA 183-93.

The district court granted Dow's motion for summary judgment, holding nearly all of the farmers' claims preempted. Pet. App. 21a. The one exception was that FIFRA did not preempt claims based on "statements made by [Dow's] employee representatives who examined [petitioners'] fields and advised them that the peanuts would grow out of the problem and that [Dow] would pay the growers for any production loss and increased expenses." *Id.* at 28a-29a. But the court held the farmers limited to the remedies specified on the label. *Id.* at 29a-30a.

The court of appeals affirmed, holding that "FIFRA expressly preempted the farmers' state law claims." *Id.* at 9a. It rested on circuit precedents announcing a rule that "FIFRA preempts state laws that either directly or indirectly impose different labeling requirements." *Id.* at 11a & n.9 (citing *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994)). The court reasoned that "the farmers' claims are expressly preempted under § 136v(b) if a judgment against Dow would induce it to alter its product

label," *id.* at 15a, even as to the "off label" claims, *id.* at 16a. It held that the farmers' claims were "all preempted by FIFRA's express preemption clause." *Id.* at 20a.

SUMMARY OF ARGUMENT

I. State damages actions are not preempted by FIFRA because the word "requirements" as understood by its context in § 136v(b) encompasses only rules issued pursuant to positive law, such as statutes and regulations. Section 136v(b) is a subset of a broader non-preemptive provision in § 136v(a), which expressly upholds the authority of States to issue "regulation[s]." By referring to "Such State" in § 136v(b), Congress specifically referred back to the regulations authorized in § 136v(a).

That construction is consistent with the broad non-preemptive thrust of § 136v(a), as well as the overall structure of FIFRA. The word "requirements" appears 75 times in the statute: in every instance, the word clearly refers to a duty imposed solely by positive law and not common law. FIFRA is therefore unlike statutes using the word "requirements" that this Court considered in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). The legislative history contains no indication that Congress intended to upset long-standing practices in States permitting compensatory damages suits against pesticide manufacturers that caused crop damage. To construe § 136v(b) as preempting the farmers' suits would be contrary to Congress's central aim in the 1972 Act to protect the public from dangerous chemicals. Because nothing in FIFRA affords compensation to parties injured by pesticides, state-law damages claims properly fill the void left by Congress.

II. Even if the Court were to conclude that "requirements for labeling or packaging" in § 136v(b) can encompass some state-law claims, the scope of § 136v(b) permits claims against pesticide manufacturers that challenge the efficacy of the product even where such efficacy claims are made on the label. In 1978, Congress expressly authorized EPA to waive determinations of whether a pesticide is effi-

cacious, and for a quarter-century the agency has in fact waived such requirements. Thus, claims contesting the efficacy of a pesticide impose no "requirements for labeling or packaging in addition to or different from" FIFRA.

That is also true with respect to misbranding. It is unlawful under FIFRA for a manufacturer to label a pesticide with false information, improper instructions for use, and inadequate warnings. State-law claims that are consistent with that federal prohibition are therefore not preempted. *See Medtronic*, 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in relevant part).

In any case, many of the farmers' specific claims – such as strict liability, negligent design, fraud, and deceptive trade practices – rest on representations by Dow having nothing to do with the Strongarm label and cannot be defended with any type of "fair warning." Those claims therefore impose no additional or different labeling requirements merely because the manufacturer makes a voluntary decision to change its label and thereby seek to avert its future liability to other purchasers. The Fifth Circuit fundamentally disregarded this Court's teaching that the proper analysis focuses on the legal duty underlying each state-law claim, and not on the open-ended inquiry into whether a damages award might somehow "induce" a manufacturer to seek a change in its label from EPA. *See Cipollone*, 505 U.S. at 523-30 (plurality op.); *Medtronic*, 518 U.S. at 492-502.

III. The farmers are entitled to sue for misrepresentations that Dow made after they used Strongarm. Dow represented that it would compensate the farmers for their damages from crop loss and expenses incurred in trying to salvage their crops. By holding that "all" of the farmers' claims are preempted, Pet. App. 20a, the Fifth Circuit's internally contradictory opinion forecloses the farmers' ability to sue for those broken promises and misrepresentations in an amount beyond the label's limitation of remedies, even though those claims do not implicate Dow's Strongarm label or any other FIFRA requirement.

ARGUMENT

I. STATE-LAW DAMAGES ACTIONS ARE NOT PREEMPTED BY FIFRA

For six decades prior to the 1972 Act, farmers routinely brought state-law actions against manufacturers for damages to their crops caused by pesticides. Nothing in the text, structure, legislative history, or purposes of that Act indicates that Congress intended to change that tradition by precluding farmers from seeking redress for the damages caused to them by pesticide manufacturers.

A. The Text Of § 136v(b) Does Not Compel Preemption Of The Farmers' Claims

As with any statute, "analysis of the scope of the preemption statute must begin with its text." *Medtronic*, 518 U.S. at 485. Although the existence of an express preemption clause does not negate the need for an analysis of implied preemption, *see Freightliner Corp. v. Myrick*, 514 U.S. 280, 288-89 (1995), analysis of the clause itself "must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

The preemption clause at issue here follows immediately after a provision that confers significant regulatory authority on States. Together those provisions read:

> **§ 136v. Authority of States**
>
> **(a) In General**.—A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this [Act].
>
> **(b) Uniformity**.—Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this [Act].

The theory underlying preemption is that state-law claims, such as the farmers' damages claims here, impose "requirements for labeling or packaging in addition to or different from those required under [FIFRA]." § 136v(b). But the text of § 136v(b) and § 136v(a) does not support preemption of such claims.

1. "Requirements" in § 136v(b) is a subset of "regulation[s]" in § 136v(a)

The word "requirements" in § 136v(b) is used as a subset of the word "regulation[s]" in § 136v(a). A State is permitted to "regulate" (§ 136v(a)) the sale or use of pesticides, but only to the extent "[s]uch State" (§ 136v(b)) does not impose "requirements" (*id.*) that are in addition to or different from those in FIFRA. The "requirements" of § 136v(b), therefore, are viewed through the lens of the "regulation[s]" a State is permitted to issue in § 136v(a). *See Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995) ("a word is known by the company it keeps").

As this Court has unanimously concluded, the term "regulations" denotes "positive enactments." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002). *See also Cipollone*, 505 U.S. at 519 ("the term 'regulation' most naturally refers to positive enactments by [legislatures and agencies], not to common-law damages actions"). As used in FIFRA, the term "regulation" is used the same way, for it would make no sense to say that a damages award acts as a "requirement" to "permit any sale or use prohibited by [FIFRA]." § 136v(a). To be sure, a state statute authorizing the sale or use of any state-registered pesticide would constitute a preempted "regulation" or "requirement" as to pesticides prohibited by EPA under FIFRA, but no court judgment could grant the same sale or use permission, which is purely a function of positive law. Whatever limits § 136v may impose on positive state labeling commands,

therefore, that section contains no textual indication of an intent to preempt state damages actions.[7]

In addition, Congress used the term "requirements" in § 136v(b) to refer to both state and FIFRA requirements. It prohibits state labeling "requirements" in addition to or different from "those required" (*i.e.*, "those [*requirements*] required") under FIFRA. It would be unnatural to read the word "requirements" more broadly in reference to a source of state law than for the federal government. *See Mohasco Corp. v. Silver*, 447 U.S. 807, 826 (1980) ("[W]e cannot . . . giv[e] the word 'filed' two different meanings in the same section of the statute.").

2. The preemptive "requirements" in § 136v(b) are narrow exceptions to broad regulatory authority conferred on States by § 136v(a)

The preemptive scope of § 136v(b) must be assessed in the context of § 136v(a), which is an "anti-preemption" provision that expressly authorizes States to regulate pesticides *more* stringently than EPA. Thus, a State (such as Texas) may completely ban the sale or use of a pesticide (such as Strongarm), even though EPA has registered the pesticide and approved its label. (A State, however, may not override federal law by permitting "any sale or use *prohibited by* [FIFRA]." § 136v(a) (emphasis added).)

As this Court stressed in *Mortier*, "§ 136v(a) . . . acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow pre-emptive overlap might occur." 501 U.S. at 614. Plainly it makes no sense to con-

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[7] This Court has squarely held that "field pre-emption cannot be inferred" from FIFRA. *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 612 (1991). "To the contrary, the statute leaves ample room for States and localities to supplement federal efforts even absent the express regulatory authorization of §136v(a). . . . The specific grant of authority in § 136v(a) . . . does not serve to hand back to the States powers that the statute had impliedly usurped." *Id.* at 613-14. It therefore is logical to read § 136v(a) and (b) as not intending to affect the common-law authority that States exercised prior to the 1972 Act.

strue § 136v(b) to foreclose the *lesser* regulatory effects that flow from damages actions that enable the pesticide manufacturer to choose to sell its products while assuming the risk of incurring common-law liability, when § 136v(a) gives States the far *greater* power to ban altogether sales and uses of the same product. Notably, the statutes at issue in *Cipollone* and *Medtronic* did not contain similar provisions conferring such sweeping regulatory authority on States, so this Court did not address whether Congress intended "requirements," in a statutory context analogous to FIFRA, to encompass the less stringent rulemaking directives of common-law liability.

3. Section 136v(b) addresses label commands, not actions that indirectly induce label changes

The limited scope of § 136v(b) also must be understood in light of the interplay between that provision and § 136v(a) and (c), which authorize States to apply indirect pressure on pesticide manufacturers that might induce a change to their labels. Holding state-law claims preempted is contrary to that intent.

Section 136v(a) permits a State to restrict or completely prohibit pesticide sales and use for any reason – including the State's perception that the label's warning is inadequate or the product is misbranded. Like a substantial damages award, those restrictions may induce pesticide manufacturers to seek EPA approval for a label alteration. Alternatively, a manufacturer may be induced to request EPA approval to change its label to promote additional pesticide uses approved by States under § 136v(c) that EPA has not approved. Section 136v(c) acts as an exception to § 136v(b) by conferring additional authority on States with respect to pesticide registrations to meet "special local needs." § 136v(c)(1). Indeed, EPA has interpreted § 136v(c) to permit States *directly* to "require supplemental labeling" when they determine a pesticide should be classified for restricted use under state law but EPA has not done so under FIFRA. 40 C.F.R. § 162.153(e)(5); *see* 46 Fed. Reg. 2008, 2011-12 (1981).

Especially in view of such authority for direct labeling regulations, any indirect pressure to change a pesticide label does not frustrate Congress's purpose of establishing nationally uniform labels. If a State bans the use of a pesticide, then any change the manufacturer makes to the label (as approved by EPA) would not be preempted; there is no reason to treat labeling changes prompted by state-law damages liability any differently. Indeed, Dow's own actions here suggest that "uniformity" concerns can readily be accommodated. After causing devastating injury to the farmers' crops, Dow rushed through a "supplemental" label addition within *seven months* after the farmers first reported injury. That supplemental label – which states that it is for distribution *only* in Texas, New Mexico, and Oklahoma – advised growers in those states with lands having a soil pH of 7.2 or greater not to use the very product that Dow had warranted the year before as usable "in all areas where peanuts are grown," JA 175, and to use it in a substantially different manner in lesser pH soils.

Congress commonly distinguishes between state positive and common law for preemption purposes. For example, the Court recently found no preemption of common-law claims under the Federal Boat Safety Act, noting that construing the Act that way "does not produce anomalous results. It would have been perfectly rational for Congress not to pre-empt common-law claims, which – unlike most administrative and legislative regulations – necessarily perform an important remedial role in compensating accident victims." *Sprietsma*, 537 U.S. at 64. The Court unanimously reached that conclusion in construing a preemption provision with a more definitive preemptive scope than FIFRA: "a State may not establish, continue in effect, or enforce a law or regulation establishing . . . or imposing a requirement." *Id.* at 58-59.[8]

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[8] *See also Cipollone*, 505 U.S. at 518 ("[T]here is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common-law damages actions."); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("The

4. Section 136v(b) must be construed applying the presumption against preemption

Any doubt about Congress's intent in using the word "requirements" – or in construing the scope of § 136v(b), *see infra* Parts II and III – must be resolved *against* preemption. The Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action," especially where "Congress has 'legislated . . . in a field which the States have traditionally occupied.'" *Medtronic*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).[9] Agriculture and consumer protection are plainly such "traditional" state-law fields.

As this Court said in the FIFRA context in *Mortier*, preemption analysis "'start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" 501 U.S. at 605 (quoting *Rice*, 331 U.S. at 230). The *Mortier* Court then applied that long-standing presumption against federal preemption of state law by holding that FIFRA does not preempt pesticide regulation by local governments, even though § 136v expressly authorizes "States" to regulate pesticides but is silent with respect to whether local governments may also do so. The Court found § 136v's "[m]ere silence" on the question "wholly inadequate to convey an express preemptive intent." *Id.* at 607. Here, too, the statute is

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effects of direct regulation . . . are significantly more intrusive than the incidental regulatory effects of such an additional award provision. . . . Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not."); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984) ("Congress intended to stand by both concepts [of federal regulation and state damage liability] and to tolerate whatever tension there was between them. We can do no less.").

[9] *See also, e.g., New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995) (applying presumption and finding no preemption) (citing *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985)); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740 (1985).

silent on preemption of damages claims, and congressional purposes underlying FIFRA are not served by broadly construing "requirements" to foreclose the types of state-law claims that were routinely brought against manufacturers to redress injuries caused by pesticides.

B. FIFRA's Structure Confirms That Congress Did Not Intend To Preempt State-Law Claims

The extensive use of "requirements" throughout FIFRA shows that Congress had no intent to preempt damages actions that might indirectly spur a pesticide manufacturer to alter the label of a faulty product. The term "requirements" is used 75 times in the remainder of FIFRA, including in the context of both labeling and state-law requirements, and each time refers only to direct commands arising out of statutory or regulatory enactments.

The use of "requirements" throughout FIFRA demonstrates that Congress understood labeling "requirements" to refer only to labeling commands imposed by statute and regulation, and it used the term "requirements" to denote a subset of "regulation[s]," a term connoting positive commands of law. "Requirements" should be construed the same way in § 136v(b). *See*, *e.g.*, *Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it appears."); *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992) ("identical terms within an Act bear the same meaning").

For example, EPA may register a pesticide only if "its labeling . . . compl[ies] with the requirements of [FIFRA]." § 136a(c)(5)(B). A pesticide is "misbranded" if its "labeling" fails to conform to the classification "requirements" imposed by § 136a(d). § 136(q)(1)(F), (G). Another provision, entitled "Requirements," bars pesticide labels that "conflict with or detract from any statement required by law or the Administrator as a condition of registration." § 136a(c)(9)(B). And § 136q(a)(1)(B) provides that EPA regulations "may require" that "the labeling of a pesticide contain requirements and procedures for the transpor-

tation, storage, and disposal of the pesticide." Because FIFRA refers exclusively to labeling "requirements" imposed under that Act, § 136v(b) should not be read more broadly to encompass state-law damages actions.

FIFRA's numerous other uses of the term "requirements" likewise encompass only positive law. Various provisions refer specifically to FIFRA's own "data requirements,"[10] "recordkeeping requirements" (§§ 136f(a), 136i-1(a)), "time requirements" (§§ 136d(b), 136w(a)(2)(C), 136w(d)(1)), and "registration requirements" (§§ 136a(h), 136m(a)(2)(A)). Additional references point to the "requirements" found in specific sections of FIFRA.[11] Other

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[10] *See* § 136a(c)(2)(A) ("data requirements . . . with respect to minor uses"); § 136a(c)(2)(B)(viii)(I)(A) ("data requirements" for registration); § 136a(c)(2)(B)(viii)(III) ("process to . . . alleviat[e] future disparities between Federal and State data requirements"); § 136a(c)(2)(E) (EPA "may waive otherwise applicable data requirements"). Other provisions address "data requirements." § 136a(h)(4)(B); § 136a-1(a)(1), (b)(4), (c)(1)(C), (f)(1), (f)(1)(B); § 136d(f)(3)(D), (f)(4); § 136q(a)(1).

[11] *See* § 136(q)(1)(F) (pesticide is "misbranded" if label omits § 136a(d) "requirements"); § 136(q)(1)(G) (same); § 136a(b)(2) ("requirements" of an experimental use permit); §136a(c)(2)(B)(iv) ("requirements that served as a basis for the notice of intent to suspend"); § 136a(c)(6) (denial of registration for failure to satisfy "requirements" of § 136a(c)(5)); § 136a(g)(1)(A) ("requirements" of section 136d); § 136a(h)(3)(C) ("requirements" of § 136a(c)(3)); § 136a-1(a)(2) ("requirements" of § 136a(c)(5)); § 136a-1(e)(1)(A) ("requirements" of § 136a and "the regulations issued under such section"); § 136a-1(e)(1)(B) (same); §136a-1(e)(1)(D) (same); §136a-1(e)(4)(A)(iv) (same); § 136a-1(g)(2)(C) ("requirements" of § 136a(c)(5)); § 136a-1(j) (exemption from "requirements" of §136a-1(d)-(f), (i)); §136g(c)(1) (civil and criminal proceedings for failing to comply with requirements of this subchapter); § 136i-1(e) (requirements of this section do not affect state or federal laws); § 136j(b)(1) (exemption from penalties for compliance with requirements of this subchapter); § 136k(b)(3) (seizure of pesticides that cause harm but comply with requirements of this subchapter); § 136q(f)(1)(C) (exemptions from requirements of this subsection); § 136w(b) (exemption from requirements of this subchapter); § 136w-1(b) ("requirements" of § 136i).

references to "requirements" point to EPA regulations[12] and other federal statutes.[13]

Significantly, FIFRA's references to "requirements" *of state law* encompass only positive law commands. *See* § 136i(a)(1) ("[T]he Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides. Such program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section . . . ."); § 136w-2(a) (referral of complaint to "State officials for their investigation of the matter consistent with the requirements of [FIFRA]"); *see also* § 136w-5 ("Each State may establish minimum requirements for training of maintenance applicators and service technicians."). And other provisions of FIFRA contain usage similar to § 136v(b)'s use of "requirements" as a subset of the positive-law "regulations" in § 136v(a). Thus, EPA "may by *regulation* . . . issue *requirements*" regarding pesticide storage and transportation. § 136q(a)(2)(A), (3)(A) (emphases added). It also "may by *regulation* . . . issue *requirements*" for disposing of certain pesticides and containers. § 136q(a)(2)(B)-(C), (3)(B)-(C) (emphases added). In sum, not a single one of the 75 uses of "requirements" from the 1972 Act or the 1978 amendments can be read to refer to common-law damages actions. Every use of "requirements" clearly encompasses commands imposed only by statute or regulation.

The *Medtronic* plurality similarly relied on the fact that neighboring subsections of the statutory provision at issue there – and unlike the statute at issue in *Cipollone* – used the term "requirements" to "refer only to statutory and

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[12] *See* § 136a(h)(3)(A)(ii) ("[r]equirements" for proposed regulations addressing antimicrobial pesticides); § 136a(h)(3)(B)(iii) ("[r]equirements" for final regulations); § 136q(a)(2)(A)-(C) (EPA authority to "issue . . . requirements and procedures"); § 136q(a)(3)(A)-(C) (same).

[13] *See* § 136a-1(g)(2)(E)(ii) ("requirements" of Federal Food, Drug, and Cosmetic Act); §136q(f)(1)(B)(iv) ("requirements" of Solid Waste Disposal Act); § 136q(f)(3) (same); § 136q(h)(1) (same).

regulatory law that exists pursuant to the [statute] itself, suggesting that the pre-empted 'requirements' established or continued by States also refer primarily to positive enactments of state law." 518 U.S. at 489. The textual evidence here, however, is far stronger than in *Medtronic*. There, the use of "requirements" in the preemption clause itself did not refer back specifically to regulations Congress authorized States to promulgate in the same manner as § 136v(b),[14] whereas here the scores of other uses of "requirements" in FIFRA support a uniform and consistent interpretation of "requirements" in § 136v as limited to those rules deriving from positive law enactments. *See also Sprietsma*, 537 U.S. at 63 (finding that "Congress preempted only positive enactments" based on context in which "law or regulation" appeared in provision).[15]

C. FIFRA's Legislative History And Purposes Reveal No Intent To Preempt Damages Actions

When FIFRA was amended in 1972 to add § 136v(b), state-law damages actions against manufacturers had been common since the advent of the chemical pesticide industry. *See supra* pp. 4-5. And it was well-settled that

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[14] The preemption clause at issue in *Medtronic* addressed "State and local requirements" in the provision's title. The substantive provision stated that "'no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device.'" 518 U.S. at 481 (quoting 21 U.S.C. § 360k(a)(1)). Unlike in § 136v(b), which cross-references a state "requirement" stemming from a "regulation" otherwise permitted in § 136v(a), the preemption clause in *Medtronic* contained no similar cross-reference.

[15] The Montana Supreme Court was persuaded by FIFRA's voluminous and consistent usage that § 136v preempts no common-law claims, and it observed that, despite the fact that many federal courts of appeals had held such claims preempted, none had "ever addressed the meaning of 'requirements' in the entire context of FIFRA . . . . It is inconceivable that Congress intended that § 136v(b) would be the only section of FIFRA in which the term 'requirements' includes the application of general rules of common law by judges and juries." *Sleath v. West Mont Home Health Servs., Inc.*, 16 P.3d 1042, 1051 (Mont. 2000).

FIFRA's labeling requirements set only minimum standards and thus did not preempt state-law damages actions for failure to warn.[16] Aware of that background, Congress thus perceived no need to include a private right of action for damages in FIFRA.

In *Mortier*, this Court held that the legislative history of § 136v(b) concerning whether local governments were preempted from regulating pesticides was "complex and ambiguous," 501 U.S. at 612, and that a "disagreement" on that issue between "the two principal committees responsible for the bill . . . falls far short of establishing that preemption of local pesticide regulation was the 'clear and manifest purpose of Congress,'" *id.* at 610. The history on the issue presented here is far clearer. According to a comprehensive review of the voluminous legislative history of the 1972 FIFRA amendments by the U.S. Department of Justice, no witness or Member of Congress ever suggested that the proposed legislation would shield pesticide manufacturers from product liability tort suits. *See* Amicus Br. for United States at 5-6, 18-19, *Etcheverry v. Tri-Ag Serv., Inc.*, No. S072524 (Cal. filed Mar. 23, 1999), *available at* https://www.citizen.org/documents/usetcheverrybrief.pdf. Indeed, there is not even a single mention of such a notion. *Id.* That omission is striking, given the testimony estimating the personal toll attributable to pesticides per year at 200 to 800 deaths and 60,000 to 80,000 injuries.[17] As the U.S. has concluded, "[g]iven

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[16] *See, e.g.*, *Hubbard-Hall*, 340 F.2d at 405 (no FIFRA preemption); *Griffin v. Planters Chem. Corp.*, 302 F. Supp. 937, 944 (D.S.C. 1969) ("Aside from the requirements set forth for the label by the Secretary of Agriculture, [defendant] had a duty to use a label, or furnish a warning commensurate with the danger."); *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387, 394 (Tex. Ct. App. 1968) (FIFRA does not "purport[] to change the common law duty to warn . . . [but] merely set[s] minimum standards").

[17] *See Federal Pesticide Control Act of 1971: Hearings before the House Comm. on Agriculture*, 92 Cong., 1st Sess. 708 (1971); *Federal Environmental Pesticide Control Act: Hearings before the Subcomm. on Agricultural Research and General Legis. of the Senate Comm. on Agri-*

that FIFRA establishes no private damages remedy for those injured by pesticides, it would be astonishing that, without any discussion, Congress could have intended to deprive injured persons of all means of relief." *Id.* at 6; *Silkwood*, 464 U.S. at 256. *See also* Amici Br. for Western Peanut Growers Ass'n *et al.*

The *Medtronic* plurality rejected a similar argument under the Medical Device Amendments, finding the argument for preemption "not only unpersuasive, [but] implausible." 518 U.S. at 487. Absent a federal private cause of action, preemption of state-law damages actions would effectively bar compensatory relief to injured persons and "would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation." *Id.* In view of the industry's position that any such liability would induce a change in the pesticide's label, affirming the Fifth Circuit's decision would produce a similarly perverse effect under FIFRA.

D. Neither The Fifth Circuit's Nor The Government's New Preemption Analysis Is Persuasive

Like other courts that have upheld a broad preemption under FIFRA, the Fifth Circuit assumed that § 136v(b)'s use of the word "requirements" necessarily ends the analysis. *See* Pet. App. 11a (citing *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 398 (5th Cir. 1999)). The court made no effort to consider the contextual placement of "requirements" in the preemption provision, as this Court did in *Medtronic*, or the overwhelming textual and contextual evidence that Congress could not possibly have meant to foreclose state lawsuits when it used the word "requirements" in § 136v(b).

In that respect, the court below followed mechanistically other court of appeals' decisions finding that FIFRA preempts state failure-to-warn damage claims, many of which

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culture and Forestry, 92 Cong., 1st Sess. 161, 168-71, 172-86 (1971); H.R. Rep. No. 92-511, at 71 (1971); S. Rep. No. 92-970, at 27 (1972).

were decided before *Medtronic*. Those cases in turn had applied *Cipollone* based largely on the fact that "requirements" appeared in both statutes. They made no serious examination of the very different statutory text and structure of FIFRA.[18] Even after this Court decided *Medtronic* – which made plain that "requirements" must be interpreted in its statutory context – some courts have considered themselves bound by pre-*Medtronic* precedent (and declined to rehear the issue *en banc*). *See*, *e.g.*, *Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 899 (8th Cir. 2002).

In *Etcheverry*, the United States recognized that the prevailing approach among federal courts contained no analytic force. In a powerful brief, the government argued that §136v(b)'s use of "requirements" did not foreclose state-law actions to redress pesticide injuries. The government now has adopted a position 180 degrees opposite to its careful, detailed, and analytical brief in *Etcheverry*, which it reiterated in *Hart v. Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000). Because the government's *amicus* briefs filed in *Etcheverry* and *Hart* were filed with the Solicitor General's authorization, *see* 28 C.F.R. §0.20(c), the government's reversal of position now is entitled to no weight or deference. *See*, *e.g.*, *Norfolk S. Ry. v. Shanklin*, 529 U.S. 344, 356 (2000) ("no such deference is appropriate" where government's position "contradicts the agency's own previous construction"); *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference depends, *inter alia*, on consistency and formality of government's position).

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[18] *See*, *e.g.*, *King v. E.I. DuPont De Nemours & Co.*, 996 F.2d 1346, 1350-51 (1st Cir. 1993); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023-25 (5th Cir. 1994); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370-71 (7th Cir. 1993); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887, 888 (8th Cir. 1994); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 559-61 (9th Cir. 1995); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1178-79 (10th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993) (per curiam).

II. PETITIONERS' CLAIMS ARE OUTSIDE THE SCOPE OF § 136v(b) PREEMPTION

Even if this Court were to conclude that the word "requirements" in § 136v(b) can include state-law damages actions, it does not follow that *all* such claims are barred. The 1972 Act did not "transform[] FIFRA into a comprehensive statute that occupied the field of pesticide regulation." *Mortier*, 501 U.S. at 612. Yet Dow's theory of preemption, as accepted by the court below, would functionally do that: any claim with even an "indirect[]" effect (Pet. App. 11a) on a label is preempted. The court failed to conduct a nuanced analysis of the farmers' claims to determine whether they are consistent with § 136v(b).

For three distinct reasons, those claims survive. *First*, Congress specifically amended FIFRA to eliminate a requirement that EPA evaluate a pesticide's efficacy, so § 136v(b)'s "requirements" do not properly encompass common-law claims addressing efficacy. *See Medtronic*, 518 U.S. at 484-85 (interpreting scope of express preemption provision in light of congressional purposes and presumption against preemption); *id.* at 507-08 (Breyer, J., concurring in part and in the judgment) (scope of word "requirement" should be informed by "read[ing] the preemption statute . . . in light of . . . basic pre-emption principles" of "'conflict' and 'field' pre-emption"); *Cipollone*, 505 U.S. at 518 (using conflict-preemption analysis to interpret scope of express preemption clause in 1965 Federal Cigarette Labeling and Advertising Act). *Second*, Congress flatly prohibited labels that are false and give inadequate instructions for use. The farmers' claims are parallel to, and not inconsistent with, those "misbranding" requirements. *See Medtronic*, 518 U.S. at 495; *see also id.* at 513 (O'Connor, J., concurring in relevant part) (state cause of action that seeks to enforce federal requirement not preempted). *Third*, the text of § 136v(b) itself only forecloses state requirements that are "in addition to or different from" "labeling or packaging" requirements imposed under FIFRA. Analysis of the elements of the farmers'

claims – which the court below did not conduct – establishes that strict liability, breach of express warranty, negligence, and fraud claims rest on legal duties that impose no alteration to an EPA-approved label.

A. EPA Has Waived Evaluation Of Whether A Pesticide Might Be Toxic To The Target Crop When Approving A Pesticide Label

Congress has expressly permitted EPA to waive any evaluation of the efficacy of pesticides prior to registration. Because FIFRA no longer imposes a duty on EPA to evaluate the efficacy of any federally registered pesticide, liability for the farmers' claims imposes no labeling requirements "in addition to or different from" those in FIFRA. The "requirements" preempted in § 136v(b), therefore, cannot include claims concerning the efficacy of pesticides. Yet the farmers' claims here for strict liability, fraud, negligence, and breach of warranty *are*, in effect, claims that Strongarm was ineffective.

1. For the past 26 years, Congress has expressly authorized EPA to register agricultural pesticides *without* evaluating whether they might cause crop damage. EPA regulations provide that a pesticide manufacturer need not submit "efficacy" data concerning: (1) "target area phytotoxicity," which is defined as whether the pesticide leaves the target crop unharmed, 40 C.F.R. § 158.540, or (2) "product performance," defined as whether the pesticide controls the target pest, *id.* § 158.640(b); *see also* U.S. Inv. Br. 4.[19] As applied to this case, those regulations mean that EPA registered Strongarm without evaluating whether it might (1) damage the farmers' peanut crop or (2) control the weeds it was designed to eradicate.

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[19] Although EPA's regulations provide that "target area phytotoxicity" data are "required for Special Review and certain public health situations," 40 C.F.R. § 158.540(b)(1), and "product performance" data are required in certain cases concerning human health or where EPA on a case-by-case basis requires it, *id.* § 158.640(b)(1), those circumstances are inapplicable here.

FIFRA's 1972 amendments allowed EPA to register a pesticide only upon evaluating its proposed label and determining that its "composition is such as to warrant the proposed claims for it." § 136a(c)(5)(A). But EPA soon discovered that efficacy review diverted scarce resources from the agency's paramount responsibilities of protecting public health and the natural environment, so it requested from Congress the authority "to waive the efficacy data requirement when appropriate" – "particularly [with regard to] agricultural pesticides." H.R. Rep. No. 95-343, at 9 (statement of EPA Administrator Costle); *see also* H.R. Rep. No. 95-663, at 18 (1977) ("The registration and reregistration process, which is the foundation of the program, has come to a virtual halt.").

In 1978, Congress amended FIFRA by conferring on EPA the authority it had requested to waive efficacy requirements. *See* § 136a(c)(5) (final two sentences). Congress made clear that "[t]his authority is expected to be used, in particular with respect to *agricultural chemicals*." H.R. Rep. No. 95-663, at 19 (emphasis added); *see also id.* at 27 (authorizing waiver "whenever the Administrator found that some other procedure for assuring the efficacy of pesticide products appeared to be sufficient").

EPA waived its review of proposed label claims relating to pesticide efficacy, explaining that the waiver would enable it to focus on EPA's "primary mandate under FIFRA . . . [,] the health and safety aspects of pesticides." 47 Fed. Reg. 53,192, 53,196 (1982); *see* 40 C.F.R. § 158.640(b)(1); 40 C.F.R. § 158.540(b)(1). The agency found that efficacy review was unnecessary because efficacy claims are "effectively regulated by the marketplace." 44 Fed. Reg. 27,932, 27,938 (1979). That is, "pesticide producers are aware that they are potentially subject to *damage suits* by the user community if their products prove ineffective in actual use." 47 Fed. Reg. 40,659, 40,661 (1982) (emphasis added). As a result, EPA reviews pesticide labels for the adequacy of claims relating to human health and the natural environment – but *not* for "target area phytotoxic-

ity," *i.e.*, the farmers' crop damage. 40 C.F.R. § 158.540. Accordingly, there is no EPA action, rule, or decision that would conflict with the farmers' suit.[20]

In 1996, after several courts had found crop damage claims preempted by FIFRA based on EPA's supposedly "rigorous label-approval process," *Taylor AG Indus.*, 54 F.3d at 560, EPA issued a public notice ("PR 96-4") explaining that "courts have erroneously concluded that because a pesticide label contained warnings regarding property damage that EPA had necessarily evaluated such warnings and found them to be truthful and adequate. . . . [T]his Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." JA 235. EPA also noted that, in previously exercising its power to waive efficacy review, it had "pointed to private legal actions for damages as one factor that would ensure that pesticide manufacturers sold an efficacious product." JA 230 (citing 47 Fed. Reg. at 40,659, 40,661).[21]

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[20] The Texas Supreme Court found these considerations persuasive in holding that FIFRA does not preempt crop damage claims. *See American Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S. Ct. 2637 (2003). Although the California Supreme Court reached a contrary conclusion, it did so based on a fundamental error that assumed EPA's efficacy data waiver did not include the "target area phytotoxicity" waiver in 40 C.F.R. § 158.540. *See id.* at 28-29 (discussing *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366 (Cal. 2000)). As the government recognizes, the "target area phytotoxocity" data waiver in 40 C.F.R. § 158.540 is part and parcel of EPA's efficacy data waiver pursuant to the 1978 FIFRA amendments. *See* U.S. Inv. Br. 4, 13.

[21] In attempting to rationalize its changing position on FIFRA preemption, the government observes that PR 96-4 was not intended to "express a view on the proper interpretation of the text of FIFRA's preemption provision." U.S. Inv. Br. 13-14 n.3. But the government cannot contest that the notice's statements regarding EPA's waiver of efficacy review are *factually* accurate. *See id.* ("[PR 96-4] makes clear that, under the general registration procedures addressed in that notice, EPA had waived review of the efficacy of agricultural pesticides in the registration process."); *id.* at 13 n.2 ("Generally, EPA does not in-

EPA's decision not to evaluate efficacy claims when registering a pesticide finds a strong parallel to *Medtronic*, where the Court unanimously found that FDA approval of a pacemaker, under a standard requiring the agency to determine only whether the device was "substantially equivalent" to another device already on the market, did not constitute a preemptive "requirement." 518 U.S. at 493-94; *see also id.* at 513 (O'Connor, J., concurring in relevant part). The preemption provision in that case applied to requirements concerning "safety or effectiveness." FDA even conducted its substantial equivalence review of the pacemaker with some regard for those concerns, but its abbreviated review did not "require" the pacemaker to take any particular form. *Id.* at 493 (majority op.). Instead, the device was approved without "running the gauntlet" of the full approval process for a novel medical device. *Id.* at 493-94.

2. EPA approved the Strongarm label without requiring Dow to take any particular form with respect to target area phytotoxicity claims. Because EPA waived that requirement, there was no FIFRA or EPA labeling "requirement" to preempt the farmers' suit.

The government suggests that Dow submitted efficacy data to EPA in seeking expedited review of its Strongarm application, but it then admits that such data were "*not* [submitted for EPA review] in the context of label approval." U.S. Inv. Br. 16 (emphasis added). Instead, it concedes Dow submitted data under an expedited review provision (called the "Reduced Risk Initiative") only "to allow [EPA] to determine whether 'risk reduction has a

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dependently evaluate a registrant's product efficacy claims pertaining to agricultural pesticides."); *accord* Letter from Jonathan Z. Cannon, General Counsel, EPA, to Douglas T. Nelson, Vice President-General Counsel, American Crop Protection Ass'n (Nov. 14, 1996) ("In the notice, EPA explains that it does not review the accuracy of label claims regarding efficacy and the potential for crop damage. . . . It appears to EPA that [certain court decisions] evidence a lack of a full understanding of EPA procedures and regulations.").

reasonable opportunity to be accomplished by adoption of the new pesticide by growers.'" *Id.* at 16 n.5 (quoting EPA PR 97-3 (JA 252)); *see also id.* at 13 n.2 (describing EPA's consideration of efficacy data under RRI as "circumscribed"). The government does not contend that EPA actually concluded, based on any such data, that Strongarm was safe for crops (or that the agency had any duty to assess such data). It is illogical to infer that EPA would fully evaluate target area phytotoxicity data under an *expedited* review provision when it undisputedly does not do so in a full review. The agency's regulations make clear that, if "part 158" does not require submission of efficacy data (it does not), then EPA does *not* "determine[] that the composition of the product is such as to warrant the proposed efficacy claims for it." 40 C.F.R. § 152.112(d).

Dow, on the other hand, appears to claim that EPA evaluated Strongarm's efficacy and relies on an inapposite EPA reference to Dow's proposed peanut "'plantback restrictions'" (*i.e.*, the required interval of time before a new crop can be planted on the same land). Dow Cert. Opp. 2 (quoting 65 Fed. Reg. 12,129, 12,133 (2000)). But EPA's statement was not made in the context of a FIFRA registration or an evaluation of the potential for crop damage. Rather, it concerns the agency's evaluation of Dow's request to establish a safe tolerance for diclosulam in the *food* supply, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346 (entitled "Tolerances for poisonous or deleterious substances in *food*; regulations") (emphasis added). *See* 40 C.F.R. Pt. 180 (entitled "Tolerances and Exemptions from Tolerances for Pesticide Chemicals in *Food*") (emphasis added); *see also* JA 233 ("EPA's concern is that the consumption of the rotated crop would increase *dietary* exposure to the pesticide residue. Rotational crop restrictions are not reviewed to determine if the rotated crop would be injured by the residual pesticide residues.") (emphasis added). Those *human*

health standards have nothing to do with the issue here: whether diclosulam causes damage to crops.[22]

In fact, the evidence specifically confirmed that "Dow AgroSciences LLC had not submitted any target area phytotoxicity studies or data on peanuts treated with diclosulam" and that the "EPA did not require Dow AgroSciences LLC to submit data concerning target area phytotoxicity for peanuts." JA 216. As an EPA agent explained to petitioners' expert, "EPA did not evaluate whether diclosulam (Strongarm) had a toxic effect on peanut plants." *Id.*[23]

To be sure, EPA has generally reserved the right subsequently to request efficacy data, but the potential for a follow-up assessment in no way affects its initial, conditional registration of Strongarm without having decided whether target-area phytotoxicity might render Dow's effi-

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[22] Although both FIFRA and EPA regulations require the agency to "publish in the Federal Register . . . a notice of each application for registration of any pesticide if it contains any new active ingredient" and to provide for public "comment," § 136a(c)(4); *see* 40 C.F.R. §§ 152.102, 152.119, it apparently did not do so for Strongarm. The only public notice petitioners have been able to locate in the Federal Register lists Dow's petition to establish a food tolerance for diclosulam, but not its registration of Strongarm. *See* 63 Fed. Reg. 64,484, 64,488-89 (1998).

[23] In a carefully worded affidavit submitted by Dow employee Dr. John J. Jachetta, Dow did not dispute that omission. *See* JA 219-23. That affidavit does not claim that Dow submitted target-area phytotoxicity studies, but it does claim that Dow submitted "studies evaluating the effects of Strongarm on Seedling emergence and vegetative vigor of *non*-target terrestrial plants." JA 223 (emphasis added). Importantly, whatever plants were involved in those studies, Jachetta surely would have highlighted studies submitted by Dow to EPA that concerned potential damage to peanuts. The omission in his affidavit is glaring. In addition, Jachetta's RRI submission to EPA contains only a brief summary of efficacy studies. Those studies appear to be focused entirely on whether the product will control weeds – not target-area phytotoxicity. *See* J. Jachetta, *et al.*, *Reduced Risk Rationale for Diclosulam Herbicide Used in the Control of Broadleaf Weeds in Peanuts* 24 (1998). (Although no discovery has occurred in this case, petitioners obtained this document from EPA through the Freedom of Information Act. Petitioners will promptly lodge this material with the Court upon request.)

cacy claims "false or misleading" and its Strongarm product "misbranded." § 136(q)(1)(A); *see also* § 136a(c)(5). The Court in *Medtronic* similarly found no preemption even though the pacemaker approved under the FDA's substantial-equivalence procedure had a continuing duty to satisfy the FDA's standards pertaining to "labeling[] and the misbranding and adulteration provisions of the Act." *Medtronic*, 518 U.S. at 493 (quoting FDA letter).[24] As in *Medtronic*, so too here the farmers' claims are not preempted. Agency inaction – based on Congress's repeal of the statutory requirement that EPA verify efficacy claims before registering a pesticide – cannot preempt in this circumstance. *Sprietsma*, 537 U.S. at 64-65 (rejecting reliance on Coast Guard's decision "not to adopt a regulation requiring propeller guards on motorboats"); *Freightliner*, 514 U.S. at 286-87 (rejecting preemption where federal agency "did not decide that the minimum, objective safety standard required by [federal statute] should be the absence of all standards, both federal and state").

Interpreting § 136v(b) to preempt state-law damages actions challenging label claims regarding pesticide efficacy creates a dilemma for EPA unintended by Congress: to divert resources away from its primary mission of protecting human health and the natural environment to regulate pesticide efficacy or to let pesticide efficacy go unchecked knowing that States are preempted from filling this void. There is no evidence that, in enacting § 136a(c)(5) and § 136v(b), Congress intended to leave pesticide efficacy unmonitored by preempting state-law claims. Because Congress wanted EPA to devote its limited resources to public health and natural environment issues, FIFRA should not be interpreted as preempting state-law damages actions regarding pesticide efficacy.

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[24] *Compare* 21 U.S.C. § 352(a) ("A drug or device shall be deemed to be misbranded . . . [i]f its labeling is false or misleading in any particular.") *with* 7 U.S.C. § 136(q)(1)(A) ("[a] pesticide is misbranded if . . . its labeling bears any statement . . . which is false or misleading in any particular").

The Court "should not impute to Congress a purpose to paralyze with one hand what it sought to promote with the other." *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 513 (1981) (internal quotation marks omitted).[25]

B. Petitioners' Claims Are Consistent With FIFRA's Misbranding Requirements

Even aside from EPA's waiver of review of efficacy claims, the farmers' claims are not preempted because they are completely consistent with FIFRA's prohibition on any distributed or sold pesticide that is "misbranded." § 136j(a)(1)(E). A pesticide is "misbranded" if its label is "false or misleading," contains inadequate "directions for use," or omits a necessary "warning or caution statement." § 136(q)(1)(A), (F), (G). State-law damages claims – even for failure to warn – would not impose a labeling or packaging requirement "in addition to or different from" those FIFRA misbranding prohibitions. § 136v(b). Instead, such claims would be consistent with the misbranding prohibitions by giving a remedy to injured farmers for the pesticide manufacturer's failure to ensure that its label is accurate, a requirement imposed by federal law.[26] To the ex-

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[25] These are not simply theoretical concerns. DDT was banned ultimately because of its hazardous environmental consequences, but not until many years after the first lawsuits were filed asserting injuries from DDT. *See supra* p. 2. Other pesticides have been the cause of deaths to persons from acute pesticide poisoning. *See* H. Wellford, *Sowing the Wind* 219-28 (1972). It is thus perfectly logical for Congress to entrust to EPA the tasks of evaluating pesticides for those harms, while leaving to private remedial enforcement through common-law suits the types of crop damage caused by pesticides. Indeed, numerous provisions of FIFRA entrust EPA with responsibility to safeguard the environment and public health, a statutory directive in sharp contrast to Congress's mandate with respect to pesticide efficacy. *See, e.g.*, § 136a(c)(5)(C), (D) (EPA to approve pesticides that do not produce "unreasonable adverse effects on the environment").

[26] This Court need not determine that the farmers are asserting that Dow violated FIFRA in its various particulars to uphold their claims under this theory. Rather, it is sufficient that the farmers allege that Dow's label falsely warranted its product. Those claims are consistent with FIFRA's general prohibition on misbranding. *See Med-*

tent Dow's actions are inconsistent with the standards imposed by federal law, a state-law suit to remedy such injuries would not be preempted, as this Court held unanimously in *Medtronic* under a preemption provision that likewise applied to state requirements "different from, or in addition to," federal law. *See* 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in relevant part).[27]

The absence of any state requirement at variance with a federal standard is made even clearer by the fact that EPA has not imposed a government-worded statement on the Strongarm label with which a state-law damages judgment might conflict. *Cf. id.* at 504 (Breyer, J., concurring in part and in the judgment) (concluding that a state-law requirement of a one-inch hearing-aid wire would be preempted if federal law required a two-inch wire). Rather, EPA permitted *Dow*'s proposed language, which claimed that "Use of Strongarm is recommended in all areas where peanuts are grown." JA 86, 108, 175. Neither FIFRA nor EPA "required" Dow to make or to prove that particular claim of efficacy. If Dow's claims of product efficacy were false, misleading, or otherwise misbranded as defined in FIFRA, then a state-law damages action relying on a parallel misbranding standard would be consistent with, and thus not "in addition to or different from," federal requirements. The mere fact that state-law claims require proof of additional elements (such as breach of a common

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tronic, 518 U.S. at 495 (rejecting preemption in situation where "precise contours of [plaintiffs'] theory of recovery have not yet been defined" because "pre-emption issue was decided on the basis of the pleadings"). Petitioners will have ample time, and Dow sufficient notice, to litigate those claims as discovery proceeds.

[27] Indeed, the government recently endorsed this reasoning in a brief to this Court (which withdrew the positions it had advanced in the *Etcheverry* case), explaining that the Court's "unanimous[]" holding in *Medtronic* means that FIFRA "does not bar common law tort claims that are based on a violation of federal regulations – *i.e.*, where federal regulations furnish the standard of care." Amicus Br. for United States at 13, *American Cyanamid Co. v. Geye*, No. 02-367 (U.S. filed May 30, 2003) ("U.S. *Geye* Amicus Br.").

law duty) would not, in itself, impose a requirement different from FIFRA; the burden, after all, would be on the injured party and not the manufacturer to establish such proof. *See Medtronic*, 518 U.S. at 494; *id.* at 513 (O'Connor, J., concurring in relevant part) ("To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ.").

FIFRA also provides that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]." § 136a(f)(2). If the mere fact that a pesticide has been registered is no defense to a misbranding charge by EPA, then there is no reason to find it a defense preempting a damages action.[28]

Enforcing a misbranding prohibition through state-law claims is also consistent with FIFRA's continuing duty on registrants to report adverse effects that may indicate the need for a change in the label. *See* 40 C.F.R. § 159.184 ("Toxic or Adverse Effect Incident Reports"); § 136d(b) (EPA may cancel registration "[i]f it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of [FIFRA]"). Accordingly, state-law damages actions support – not undermine – the federal mislabeling requirements. *See* U.S. Inv. Br. 4 ("EPA requires the registrant, after a pesticide has been registered, to report incidents of known harm to non-target organisms, such as crops, if the pesticide label does not provide adequate notice of the risk of such harm."). State-law claims provide a means for manufacturers to assess which incidents of pesticide harm merit reporting to EPA.

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[28] In a state damages suit, the plaintiff bears the burden of persuasion, whereas in an EPA cancellation or suspension action the pesticide manufacturer "has a continuing burden of proof to establish that its product is entitled to registration." *Dow Chem. Co. v. Ruckelshaus*, 477 F.2d 1317, 1324 (8th Cir. 1973); *see* 40 C.F.R. § 164.80(b).

C. The Farmers' Claims Do Not Add "Different" Requirements Under § 136v(b)

Even if preemption were not avoided by EPA's waiver of efficacy review or the farmers' state-law claims imposing only parallel requirements to FIFRA, their suit still would not be barred. Proof of the elements of the farmers' claims does not impose requirements "in addition to or different from" FIFRA's labeling or packaging requirements.

1. The strict liability claims are not preempted

The farmers allege that Strongarm was at all relevant times within the exclusive control of Dow when it was "designed, formulated, developed, produced, manufactured and sold." JA 189. Dow therefore is liable for defective design in the rendering of an unreasonably dangerous product under state strict liability principles. The court below deemed that cause of action equivalent to a "failure to warn" claim subject to preemption. Pet. App. 19a. It reasoned that, to avoid future liability, a manufacturer would have to alter the label, an act the court presumed would be foreclosed under § 136v(b). *Id.*

The error in the court's analysis, however, is that breach of a duty – a "failure to warn" – is not dispositive in analyzing a strict liability claim. In fact, the elements of strict liability are a defective product that was unreasonably dangerous, the defect arose when the product was in the defendant's control, and injury to the plaintiff. *See Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 336-38 (Tex. 1998) (rejecting argument that fair warning can foreclose strict liability claim "as a matter of law"). Strict liability claims "mak[e] the seller subject to liability to the user or consumer *even though he has exercised all possible care in the preparation and sale of the product.*" *Restatement (Second) of Torts* § 402A cmt. a (1965) (emphasis added). Under Texas strict liability law, the warning contained on a label is at best a factor for the jury to consider, and not a dispositive consideration as a matter of law. *See Uniroyal*, 977 S.W.2d at 336 ("'[W]hen a safer design can

reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. . . . Warnings are not . . . a substitute for the provision of a reasonably safe design.'") (quoting *Restatement (Third) of Torts: Product Liability* § 2, cmt. *l* (1998)) (emphasis omitted).

Moreover, in this case, Dow marketed Strongarm to west Texas farmers whose lands have a pH of 7.2 or higher. *See* JA 125, 179. Dow has now admitted in its supplemental label that Strongarm is *never* safe to use in such soils. *See* JA 181 ("Do not apply Strongarm to soils with a pH of 7.2 or greater."). This is not a case, therefore, where a label warning could ever make the product safe for use on farms with high pH soil. Because only a redesign of the product could do so, the farmers' claims are completely unaffected by any type of failure to warn theory. It is illogical for Dow to contend that it may market an unreasonably dangerous product and then claim preemption because a label warning could have said not to use the product at all. Indeed, the result of a damages action confirming what Dow has now admitted – that Strongarm can *never* be used in soils with a pH of 7.2 or greater and that *no* label warning could render it safe for use there – would at most have only the indirect effect of banning or restricting the use of the pesticide in those areas, which is precisely the type of direct authority § 136v(a) preserves for States.

Even in reversing its position on FIFRA preemption, the U.S. acknowledges that strict liability claims should survive. *See* U.S. *Geye* Amicus Br. at 13 ("[A] claim based on strict liability . . . need not be based on statements in labeling at all."). Because a strict liability claim does not contain as an element any breach of duty or failure to warn on the manufacturer's part, common-law liability for such a claim cannot impose a "requirement" with respect

to labeling.[29] Such claims were routinely upheld against pesticide manufacturers before and after the 1972 Act.[30] The same result should govern now.

2. The express warranty claims are not preempted

The farmers allege breach of warranty (including claims under the Texas DTPA, which "establishes a remedy for the breach of an independent warranty," Pet. App. 17a) based on express warranties provided by Dow (1) on the label and (2) off the label and before the sale. *See* JA 185-89. Those warranty theories are not preempted, however, because FIFRA imposes no "requirements" with respect to

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[29] Contributory negligence thus ordinarily is not a defense to a strict liability claim, except when the injured party "discovers the defect and is aware of the danger" and nonetheless "proceeds unreasonably to make use of the product and is injured by it." *Restatement (Second)* § 402A cmt. n. The dramatic changes in the Strongarm label in 2001 all but concede that the product was not suited for use on petitioners' farms, *see supra* pp. 11-12, so the 2000 label could not have given the farmers the requisite notice that would establish contributory negligence. The farmers also allege strict liability under *Restatement (Second)* § 402B, which provides strict liability when the seller of chattels makes "a misrepresentation of a material fact concerning the character or quality of a chattel sold by him" that causes injury, even in the absence of a fraudulent or negligent statement. *See* JA 189.

[30] *See*, *e.g.*, *Streich v. Hilton-Davis*, 692 P.2d 440 (Mont. 1984) (sufficient evidence to hold potato sprout suppressant manufacturer liable for negligence, breach of implied warranty, and strict liability for failure to warn of side effects harmful to potato crop); *Mortensen v. Chevron Chem. Co.*, 693 P.2d 1038 (Idaho 1984) (affirming JNOV for fungicide manufacturer against strict liability claim by buyer that chemical damaged seed potatoes because no proof that product was defective); *Shields v. Morton Chem. Co.*, 518 P.2d 857 (Idaho 1974) (reversing judgment for manufacturer of pesticide-fungicide for breach of warranty and strict liability because trial judge wrongly instructed jury that contributory negligence applied to both counts, when it applies only to negligence); *Rose v. Buffalo Air Serv.*, 104 N.W.2d 431 (Neb. 1960) (chemical company strictly liable for mispackaging chemicals to be sprayed on crops); *Chapman Chem. Co. v. Taylor*, 222 S.W.2d 820 (Ark. 1949) (manufacturer held strictly liable for breaching duty to test for crop damage caused by extrahazardous chemical).

express warranties. But, having made such warranties, Dow was obliged to make them true.

First, the label expressly provides that "Dow AgroSciences *warrants* that this product . . . is reasonably fit for the purposes stated on the label." JA 111 (emphasis added); *see also* JA 111-12. Indeed, Dow admitted, and the district court held, that "Strongarm's label provisions . . . provided a limited express warranty." CA App. 313; Pet. App. 26a n.1; *see also* JA 208. The "purposes" to which Dow's express warranty refers include the label representation that the "[u]se of Strongarm is recommended in *all* areas where peanuts are grown." JA 108, 175 (emphasis added). *Second*, the farmers relied on off-label representations made prior to their purchase of Strongarm by Dow's agents, who trumpeted that Strongarm was reasonably fit for use on peanuts and would yield "excellent" results in west Texas soil.[31] Under neither theory are the farmers' claims preempted.

a. The court based its conclusion that the on-label express warranty claim was preempted on the ground that the farmers' success in a damages suit "would provide a manufacturer with a strong incentive to alter its label to avoid future liability." Pet. App. 16a. That conclusion went beyond the far more limited text of § 136v(b), which preempts only state-law "requirements" that differ from or add to FIFRA "requirements" – but not claims that might induce a pesticide manufacturer to alter its product label.

As the *Cipollone* plurality instructed, the court should instead have assessed whether the "legal duty that is the predicate of the common-law damages action constitutes a [state-law] 'requirement'" under the preemption provision. 505 U.S. at 523-24. Because "[a] manufacturer's liability

[31] The evidence on this point is developed as to some of the farmers through affidavits. *See* JA 147-48, 152-53, 157-58. The absence of evidence as to other farmers at this early stage of the litigation (prior to full discovery) should not foreclose other petitioners on remand from advancing claims based on this theory of liability.

for breach of an express warranty derives from, and is measured by, the terms of that warranty . . . , the 'requirements' imposed by an express warranty claim are not 'imposed under State law,' but rather imposed *by the warrantor*" and thus are not preempted. *Id.* at 525 (alteration omitted); *see also id.* at 525 n.23 ("express warranty claims . . . sound in contract rather than in tort").

Under that analysis, the on-label, express warranty claims are not preempted "labeling requirements" because they are not imposed under state law. Instead, they derive solely from Dow, the warrantor. *See id.* at 526 ("That the terms of the warranty may have been set forth in advertisements rather than in separate documents is irrelevant to the pre-emption issue . . . because, although the breach of warranty claim is made 'with respect to advertising,' it does not rest on a duty imposed by state law.") (alteration omitted); *see American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228 (1995) (breach of contract suit not preempted by Airline Deregulation Act because "terms and conditions airlines offer and passengers accept are privately ordered obligations") (citing *Cipollone*, 505 U.S. at 526 (plurality op.)). Because nothing in FIFRA required Dow expressly to "warrant[]" that Strongarm "is reasonably fit for the purposes stated on the label" (JA 111), it is legally irrelevant that Dow felt "induce[d]" (Pet. App. 17a) to change its label to remove that warranty.

b. The Fifth Circuit also erred in holding that Dow's pre-sale, off-label statements promising the farmers "excellent" results in west Texas soils are preempted because they did not "deviate[]" from Dow's label claim that Strong-arm was "recommended in all areas where peanuts are grown" (JA 108, 175). *See* Pet. App. 17a. If those oral representations by Dow's agents merely reflect the label contents, then they should be enforceable just like the on-label warranty voluntarily provided by Dow. In any case, whether or not the off-label statements differed from the label, claims that those representations are false would

not be preempted because § 136v(b) does not preempt *any* off-label representations.[32]

Even assuming § 136v(b) could be read to preempt off-label claims that are similar to on-label claims, the pre-sale, off-label representations here were substantially different. While the label "recommended" Strongarm for use in "all" areas, the pre-sale, field-day representations were far more specific: they promised that Strongarm was "excellent" for use in "west Texas" soils. JA 147, 152, 190-91. Plainly, the farmers were interested in knowing whether Strongarm would be effective on their own lands, and that is the assurance they received from Dow, whose agents claimed that Strongarm was not merely recommended but would be "excellent" for their west Texas peanut crops. To be sure, the geography covered by the original label is broad enough to cover west Texas, but any farmer would know that soil, climate, and other essential farming conditions will vary by geography. (Indeed, that is borne out here by Dow's subsequent action: within months of the farmers' disastrous experience, Dow sought EPA approval to alter the label to exclude or substantially limit use in the areas in which Dow had once claimed Strongarm would yield "excellent" results.[33])

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[32] Even the federal government appears to accept this argument for non-preemption. In *Geye*, the government noted that "[m]agazine advertisements, as well as many types of brochures, are not within FIFRA's express definition of 'labeling.'" U.S. *Geye* Amicus Br. at 11. The government then notes that any evidence based on such off-label statements would not be preempted and would be admissible to establish liability for non-preempted claims. *See id.* at 11-12. Thus, to the extent the farmers' claims stem from off-label statements – which they undisputedly do (JA 190) – FIFRA does not preempt them even under the government's revised position.

[33] In the court below, Dow asserted (using a thesaurus) that the words "excellent" and "recommend" were synonymous. Appellee's Br. 36-37. There is no merit to that position. An "excellent" product is one that "excel[s] or exceed[s] in kind or degree," or is "meritoriously near the standard or model." *Webster's Third New International Dictionary* 791 (2002). By contrast, to "recommend" is to "praise" or "to mention

3. The fraud claims are not preempted

The farmers' fraud claims are based on the same types of representations as their express warranty claims, and are backed by the allegation and evidence that Dow marketed Strongarm to the farmers and recommended it for "all" areas despite having knowledge that scientific studies had shown diclosulam to be toxic to peanuts grown in the high pH soils commonly found in Texas, New Mexico, and Oklahoma. *See supra* pp. 8-9. As with the express warranty claims, the court below erred in holding the pre-sale representation claims preempted. *See* Pet. App. 16a-17a.

The court's overbroad focus trained only on whether success would "provide a manufacturer with a strong incentive" to alter its label "to avoid future liability." *Id.* at 16a. The court failed to assess the source of the legal duty for fraud, which *Cipollone* makes clear has nothing to do with labeling, but rests "on a more general obligation – the duty not to deceive." 505 U.S. at 528-29 (plurality op.). The *Cipollone* plurality found that fraud claims based on statements made in advertising were not preempted, even though the 1969 Public Health Cigarette Smoking Act prohibited state-law "requirement[s]" "with respect to . . . advertising." *Id.* at 515. "Unlike state-law obligations concerning the warnings necessary to render a product 'reasonably safe,' state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity." *Id.* at 529.

That analysis compels the conclusion that the farmers' fraud claims here, whether based on on-label or off-label representations, are not preempted. Indeed, the farmers' claim that Dow knew diclosulam was inappropriate for use in high pH soils is indistinguishable from the claim that

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or introduce as being worthy of acceptance, use, or trial." *Id.* at 1897. Dow's oral representations therefore greatly exceeded the "praise" offered on its label. Accordingly, holding Dow liable for those oral representations in no way would be "in addition to or different from" any labeling "requirements."

Cipollone held was not preempted, which alleged that cigarette manufacturers "possessed[] but had ignored and failed to act upon medical[] and scientific data indicating that cigarettes were hazardous to the health of consumers." *Id.* at 510 (internal quotation marks omitted). *See also Nelson v. Najm*, 127 S.W.3d 170, 175-76 (Tex. App. 2003) (warranty or "as is" provision invalid to negate fraud claim based on concealment of "a known fact").[34]

4. The negligence claims are not preempted

The farmers assert claims for negligence in the "development, testing, manufacture, production and promotion of Strongarm." JA 185. Because their theories concern the formulation and promotion of Strongarm, there is no conflicting FIFRA requirement. The Fifth Circuit's rationale for holding this claim preempted was that it is "simply a disguised claim for failure to warn." Pet. App. 19a. But because Dow's inducement to change its label can address only one theory for negligence – a breach of duty to promote accurately its products – there is no basis for preempting the farmers' claims for negligent testing, development, and manufacture of Strongarm as imposing a requirement in addition to or different from the label. *See*, *e.g.*, *Quest Chem. Corp. v. Elam*, 898 S.W.2d 819, 820-21 (Tex. 1995) (per curiam) (noting that claims against pesticide manufacturer for negligent testing, manufacturing, and formulating should "escape FIFRA preemption" under Texas law because those claims are not based on

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[34] Although Dow claimed below that the label's limitation of remedies provision would in any case limit recovery to replacement of the product or refund of the purchase price, it is black-letter law that public policy prevents a manufacturer from limiting its liability for its own fraud. *See Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486, 505 (Tex. 2001) ("Helena's liability-limitation clauses cannot preclude the Wilkinses' lost-profit recovery for nonwarranty representations or unconscionability."); *Western Union Tel. Co. v. Edsall*, 63 Tex. 668, 1885 WL 7106, at *5 (1885) (enforcing limitation of liability clause on back of telegraph form only "in the absence of fraud").

"alleged failure to provide adequate warnings and instructions" on the label).

Moreover, as with the strict liability claims, because Dow admits that Strongarm is *never* safe to use in soils with a pH of 7.2 or greater, the negligence claims cannot be negated by a defense of inadequate warning that, when followed, would make the product safe for use. *See Cipollone*, 505 U.S. at 524-25 (plurality op.) (no preemption of "claims that rely solely on [maker's] testing or research practices or other actions unrelated to advertising or promotion"). And, because § 136v(a) empowers States directly to restrict pesticide sale or use, a damages suit that indirectly does so should not be preempted even if it might induce a label alteration. Section 136v(b) should not be read to undercut a State's express authority under § 136v(a), especially in areas traditionally regulated by States such as agriculture and consumer protection.

This is a classic case of inadequate testing, as evidenced by Dow's subsequent amendment to its Strongarm label to provide special instructions for use (or to prohibit use altogether) in Texas, New Mexico, and Oklahoma. Dow's theory of FIFRA would allow it to use the unfortunate farmers – to whom Dow marketed its new product directly with great fanfare at the Field Days – to perform its field testing, with little if any responsibility for the devastating consequences (including, for some, bankruptcy). The contrary decision of the court below creates a classic Catch 22. The label says on its face that it is "registered" with EPA and that its "approved uses" include "all areas where peanuts are grown." JA 107-08, 175. Thus, a farmer reasonably must rely on the EPA-approved pesticide label to obtain the product because without EPA approval the product cannot be sold. But, if he relies on the label's assurance that the product will work, then the law tells him, in effect, that he was crazy to have done so.

III. CLAIMS CHALLENGING POST-USE, OFF-LABEL STATEMENTS ARE NOT PREEMPTED

A last set of claims concerns representations by Dow after Strongarm had been used. *See* JA 190-91. Specifically, the farmers alleged that Dow had committed fraud, fraudulent inducement to contract, and breach of express warranty by promising to compensate the farmers for any damages they sustained from using Strongarm. They also contended that those post-use statements estopped Dow from claiming label defenses. *See id.* The Fifth Circuit erred in holding that the farmers' claims stemming from Dow's post-use representations are preempted. Pet. App. 16a-17a, 20a (fraud claims preempted).

The district court found that "FIFRA does not preempt these claims" because the "off-label remarks do not repeat any information found on the Strongarm label." Pet. App. 29a; *cf. Cipollone*, 505 U.S. at 525-26 (plurality op.) (If "a manufacturer expressly promised to pay a smoker's medical bills if she contracted emphysema, the duty to honor that promise could not fairly be said to be 'imposed under state law,' but rather is best understood as undertaken by the manufacturer itself.").[35] That conclusion was plainly correct, but the Fifth Circuit's overbroad opinion holds that "the farmers' claims for breach of warranty, fraud, DTPA, defective design and negligence are *all* preempted."

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[35] The district court subsequently has treated the court of appeals' judgment as affirming the dismissal of *all* of petitioners' claims on preemption grounds. Over the farmers' objection, the court returned all funds paid into the court's registry by Dow for damages resulting from, *inter alia*, its post-use representations, on the basis that petitioners had no more live claims for which a deposit would be warranted. *See* JA 226-27. This Court therefore should hold that the farmers' post-use claims also are not preempted, and permit the parties to litigate what effect, if any, the label's limitation of remedies provision has on those claims. The Fifth Circuit's suggestion that the farmers did not seek appellate review of the district court's determination on that point, *see* Pet. App. 17a n.15, is plainly contradicted by the farmers' opening brief below. *See* Appellants' Br. 51-55; Appellee's Br. 57-62; *see also supra* n.34 (purported limitation of liability for fraud is void).

Pet. App. 20a (emphasis added). The court based that view on the ground that "success on such claims would necessarily induce Dow to alter its product label." *Id.*

The court's holding is clearly erroneous. The farmers had used Strongarm and were relying on post-use representations that Dow would remedy their injuries from that use. Such theories of fraud, fraud in the inducement, warranty, estoppel, and waiver have nothing to do with the label. Whether Dow experiences any "induce[ment]" to change the label as a result of its post-use representations to the farmers stems not from any FIFRA requirements – which are completely silent on the question of what a manufacturer's legal responsibilities are to its consumers once its product is used – but rather from the self-interest of the manufacturer. This Court has never sanctioned preemption on the theory that a private-party manufacturer can exonerate itself from common-law liability by its voluntary actions not compelled by federal law.

CONCLUSION

The court of appeals' judgment should be reversed.

Respectfully submitted,

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