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 COURTS OF APPEALS
FOR THE FIFTH CIRCUIT

AMICUS CURIAE BRIEF OF THE DEFENSE RESEARCH INSTITUTE IN SUPPORT OF RESPONDENT

JAMES L. MOORE*
GLEN SHU
MATTHEW W. CALIGUR
BAKER & HOSTETLER LLP
1000 Louisiana, Suite 2000
Houston, TX 77002
(713) 751-1600

PATRICK LYSAUGHT
BAKER STERCHI COWDEN
& RICE, LLC
Crown Center, Suite 500
2400 Pershing Road
Kansas City, MO 64108-2504
(816) 471-2121

Attorneys for Amicus Curiae

* *Counsel of Record*

191113

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INTEREST OF *AMICUS CURIAE*

The Defense Research Institute ("DRI") is an organization with members throughout the United States numbering in excess of 21,000. It seeks to advance the cause of the civil justice system in America by ensuring that the concerns of the defense bar and potential defendants are properly and adequately represented. These objectives are accomplished through the publishing of scholarly material, educating the bar by conducting seminars on specialized areas of law, and through testimony before Congress and state legislatures on select legislation impacting the civil justice system. DRI provides a forum for the networking of state and local defense organizations who share a concern for the proper and efficient operation of the civil justice system.[1]

SUMMARY OF THE ARGUMENT

Petitioners are peanut farmers in Texas who claimed that their peanut crops were damaged by an herbicide named Strongarm, which is manufactured and sold by Respondent, Dow Agrosciences LLC ("Dow"). Dow filed a declaratory judgment action in the United States District Court for the Northern District of Texas (Lubbock Division) against the Petitioners asking the court to declare, *inter alia*, that all of the farmers' causes of action are expressly and impliedly pre-empted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136, *et seq.* The Court granted the summary judgment on pre-emption and other grounds.

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1. Pursuant to Rule 37(6) of the Supreme Court of the United States, DRI states that counsel for Petitioner and Respondent had no part in authoring any portion of this brief. No one other than DRI made a monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37(3)(a) of the Supreme Court of the United States, DRI states that all parties to this case have consented to the filing of amicus curiae briefs.

The farmers (Petitioners) then appealed to the Fifth Circuit, which found that all of the claims were pre-empted under the express pre-emption doctrine because, after analyzing each cause of action, the Court determined that all of the claims boiled down to the contention that Strongarm damaged peanut crops in soil with a pH level over 7.0, an effect not disclosed to the Petitioners on the FIFRA mandated label. The Court found that success on these claims would induce Dow to change its EPA-approved label, and thus, were pre-empted under FIFRA.

The Fifth Circuit correctly affirmed the judgment of the trial court that the claims made by the Petitioners are pre-empted under the express pre-emption doctrine. The lower court properly applied the rules of law set forth in this Court's opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) in finding that the Petitioners' claims are expressly pre-empted.

In addition to express pre-emption, the Court can and should consider implied pre-emption under FIFRA. Because of the EPA's pervasive registration and labeling requirements governing pesticides like Strongarm, Petitioners' claims are barred under principles of implied conflicts pre-emption. For this additional reason, the Court should affirm the Fifth Circuit's opinion, and hold that the Petitioners' claims are barred on the basis of either express or implied pre-emption.

ARGUMENT

A. FIFRA Expressly Pre-empts Petitioners' Claims

1. The Text Of § 136v(b) Compels Pre-emption

Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. Since this Court's decision in *McCulloch v. Maryland*, 17 U.S. (4 Weat.) 316, 427 (1819), state law that conflicts with federal law is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

The plain meaning of FIFRA's express pre-emption clause mandates pre-emption of certain state law claims. Section 136v of FIFRA 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 subchapter.
>
> (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 subchapter.

7 U.S.C. § 136v. The plain meaning of the express pre-emption clause in FIFRA demonstrates that Congress intended to pre-empt certain state law claims. That clause mirrors the pre-emption statute in the Public Health Cigarette

Smoking Act of 1969 (the "1969 Smoking Act") that this Court considered in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). This Court addressed whether the 1969 Smoking Act and its 1965 predecessor pre-empted the plaintiff's common-law claims against the cigarette manufacturers. *Id.* at 508. The 1965 and 1969 Smoking Acts required manufacturers to place the following warning (or a variation) on every package of cigarettes sold in the United States: "WARNING: THE SURGEON GENERAL HAS DETERMINED THAT CIGARETTE SMOKING IS DANGEROUS TO YOUR HEALTH." *Id.* The 1965 version of the federal statute contained a narrow pre-emption provision as follows: "No statement related to smoking and health shall be required in the advertising of [properly labeled] cigarettes." *Id.* at 518. The Public Health Cigarette Smoking Act of 1969, which modified the 1965 Act, contains a broader express pre-emption provision that reads as follows:

> (b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provision of this Act.

Id. at 515 (citing § 5(b) of the Public Health Cigarette Smoking Act of 1969). The language of the express pre-emption clauses in the 1969 Smoking Act and FIFRA are strikingly similar. The Seventh Circuit has suggested that "not even the most dedicated hair splitter could distinguish these statements." *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993).

In both pre-emption clauses, this Court reasoned that the pre-emptive scope of the 1965 and 1969 Acts is "governed entirely by the express language" in the pre-emption clause. *Id.* at 517. Specifically, this Court stated,

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a reliable indicum of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation.

Cipollone, 505 U.S. at 517 (internal quotations and citations omitted).

This Court determined that the 1965 Act's pre-emption clause, which contained the phrase "statements" instead of "regulations," merely prohibited state rulemaking bodies from mandating "positive enactments by legislatures or administrative agencies that mandate particular warning levels." *Id.* at 519. In contrast, the Court determined that 1969 Smoking Act's pre-emption statute, which prohibited "requirements" to preclude state regulation either by statute or by common law. *Id.* at 521-22. Even though portions of the legislative history suggested that Congress was primarily concerned with positive enactments, this Court gave effect to the plain meaning of the statute and determined that no "good reason [exists] to believe" that Congress meant less than what it said. *Id.* at 522.

Like the 1969 Smoking Act, FIFRA prohibits "any requirements" made by a state that relate to pesticide labeling. 7 U.S.C. § 136v(b). Because of the similarity between the pre-emption provisions in the 1969 Smoking Act and FIFRA, every federal circuit court that has considered FIFRA pre-emption

since *Cipollone* has held that FIFRA expressly pre-empts failure to warn or labeling claims.[2]

2. *Medtronic* Does Not Change The Pre-emption Analysis Of *Cipollone*

Petitioners and their Amici argue that this case should be controlled by this Court's opinion in *Medtronic v. Lohr*, 518 U.S. 470, 484 (1996), in which the Court interpreted the pre-emption provision in the Medical Device Amendments ("MDA"). The pre-emption statute in the MDA stated as follows:

> § 360k. State and local requirements respecting devices
>
> (a) General Rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may

---

2. *See Lowe's Home Ctrs., Inc. v. Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002), *reh'g and reh'g en banc denied*, 61 Fed. Appx 673 (11th Cir. 2003); *Netland v. Hess & Clark, Inc.* 284 F.3d 895 (8th Cir. 2002), *cert. denied*, 123 S. Ct. 415 (2002); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Hawkins v. Leslie's Poolmart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Andrus v. AgrEvo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *Nat'l Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999); *Kuiper v. Am. Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997); *Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Welchert v. Am. Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995); *Lowe v. Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887 (8th Cir. 1994); *MacDonald v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *Worm v. Am. Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993); *King v. E.I. DuPont de Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993), *cert. denied*, 510 U.S. 985 (1993); *Shaw*, 994 F.2d 364; *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993), *cert. denied*, 510 U.S. 913 (1993); *Arkansas-Platte & Gulf P'ship v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993), *cert. denied*, 510 U.S. 813 (1993).

establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a state or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions; and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k.

This Court's analysis of whether pre-emption exists under this statute was similar to the analysis conducted in *Cipollone.* Although the examination of the pre-emption statute must begin with its text, the interpretation of that language does not occur in a contextual vacuum, but instead is informed by two presumptions about the nature of pre-emption. *Lohr*, 518 U.S. at 485. First, the Court presumes Congress does not cavalierly pre-empt state-law causes of action. *Id.* Second, the purpose of Congress is the ultimate touchstone in every pre-emption case and any understanding of the scope of a pre-emption statute must rest primarily on "a fair understanding of congressional purpose." *Id.* at 486. Congressional purpose is determined from the structure and purpose of the statute as a whole. *Id.*

This Court determined the Congressional purpose in enacting the express pre-emption clause of the MDA by examining the unique grant of authority that Congress delegated to the Food and Drug Administration ("FDA") in determining the scope of pre-emption under § 360k(b) the MDA. This Court found the MDA pre-emption clause differed from the 1969 Smoking Act's pre-emption clause:

> Unlike the statute construed in *Cipollone*, for instance, pre-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal "requirement." Because the FDA is the federal agency to which Congress has delegated its authority to implement the provision of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," and therefore, whether it should be pre-empted. For

> example, Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA—an authority that necessarily requires the FDA to assess the pre-emptive effect that the Act and its own regulations will have on state laws . . . The ambiguity in the statute—and the congressional grant of authority to the agency on the matter contained within it—provide a "sound basis," . . . for giving substantial weight to the agency's view of the statute . . .
>
> The regulations promulgated by the FDA expressly support the conclusion that § 360k "does not pre-empt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the Act."

Medtronic, 518 U.S. at 496-97 (citations omitted). FIFRA, unlike § 360k(b) of the MDA, does not grant the EPA authority to exempt a state from the express pre-emption clause of § 360k(a). Because FIFRA does not provide for such a waiver, the express pre-emption clause in FIFRA is automatic and self-executing. Therefore, the pre-emption provision in FIFRA tracks the pre-emption provision from the 1969 Smoking Act interpreted in *Cipollone* rather than the MDA provision that is the subject of *Medtronic*. Therefore, this Court should follow the analysis in the *Cipollone* opinion to find express pre-emption in this case.

3. The Scope Of FIFRA Pre-emption Covers All Label-Based Claims

DRI does not contend that FIFRA expressly pre-empts all possible claims related to agricultural pesticides. However, DRI contends that FIFRA expressly pre-empts all claims based on the FIFRA-required label. Whether a claim is label-based or

not label-based does not depend on the name of the claim, but instead depends upon a case-by-case determination of the relief sought by the claimant. If a plaintiff's claim challenges the FIFRA-required label, or if the effect of the claim would induce the manufacturer to alter the FIFRA-required label, then the claim is expressly pre-empted. If the plaintiff's claim does not challenge the FIFRA-required label or induce the manufacturer to alter the FIFRA-required label, then the claim is not expressly pre-empted. For example, a claim that a manufacturer failed to follow the EPA-approved formula for a pesticide is not label-related; and, therefore, FIFRA pre-emption does not apply. However, a claim that a manufacturer failed to warn users that a pesticide should be used only in certain soils (the allegation in this case) is clearly label-related, and FIFRA pre-emption applies.

a. All Claims That Would Induce A Manufacturer To Alter Its Label Are Pre-empted

The court of appeals below held that FIFRA expressly pre-empted all of Petitioners' claims (breach of warranty, fraud, deceptive trade practices, strict tort liability and negligence) "because success on such claims would necessarily induce Dow to alter its product label." *Dow Agrosciences LLC v. Bates*, 332 F.2d 323, 333 (5th Cir. 2003), *cert. granted*, 72 U.S.L.W. 3184 (June 28, 2004). The lower court's reasoning follows this Court's analysis in *Cipollone*. The petitioner-plaintiff in *Cipollone* argued that common-law damage actions do not impose "requirements or prohibitions" (the language in the pre-emption statute of the 1969 Smoking Act), but this Court disagreed. This Court has said, "[state] regulation can be as effectively asserted through an award of damages as through some form of preventative relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Cipollone*, 505 U.S. 504, 521 (1992)

(citing *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). If Petitioners in Texas may recover on state law claims based upon a warning label approved by the EPA, the obligation to pay the award of damages may cause Dow to alter its product label, and this would defeat the Congressional purpose in the "uniformity" sought by the express pre-emption clause of 7 U.S.C. § 136v(b).

Amici for Petitioner suggest that because FIFRA specifically regulates false or misleading statements, state tort claims for misrepresentation or fraud are not "different" than FIFRA's requirements, but merely provide a different remedy. It is exactly that possibility—the risk of a "different remedy"—that might compel a manufacturer to alter their label contrary to the intent of the pre-emption clause of FIFRA. This Court has previously recognized that allowing a different remedy, as determined by individual juries across the country, will disrupt any uniform approach. "This policy [of uniformity] by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say when different juries in different States reach different decisions on similar facts." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000). As Justice Breyer has commented,

> The effects of the state agency regulating and the state tort suit are identical. To distinguish between them for pre-emption purposes would grant greater power (to set state standards 'different from, or in addition to' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes. Where Congress likely did

> not focus specifically upon the matter, I would not take it to have intended this anomalous result.

Lohr, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment).

The claims asserted by Petitioners constitute label-based claims. Petitioners do not claim the Strongarm product is defective in all applications, but merely in soil with a pH level over 7.0. Petitioners essentially claim that the FIFRA mandated label should contain a warning not to apply the product to soil with a pH level over 7.0. Petitioners' success on these claims would induce Dow to change its EPA-approved label. Thus, the lower court correctly determined that Petitioners claims are label-based, and are therefore expressly pre-empted by FIFRA.

b. Label-Based Claims Related To Efficacy Are Pre-empted

Petitioners and their Amici argue that efficacy claims are not pre-empted because Congress amended FIFRA in 1978 to allow the EPA to waive the submission of efficacy data during the registration of a pesticide. *See* Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 5, 92 Stat. 819. However, this data submission waiver does not alter the plain meaning of § 136v(b), which states, "[A] state shall not impose or continue in effect *any* requirements for labeling or packaging *in addition to or different from* those required under this subchapter." 7 U.S.C. § 136v(b) (emphasis added). The Fifth Circuit reasoned that allowing a state to create a labeling requirement by authorizing a state law tort claim linked to the specification of a label, even where the EPA has elected not to impose such labeling requirements, would clearly impose a requirement "in addition to or different from those" required under FIFRA. *Bates*, 332 F.2d at 331.

Petitioners' efficacy claims are subject to FIFRA's express pre-emption clause if they are related to the content of the Strongarm label. *Id.*

Although the EPA may initially waive the submission of efficacy data for pesticides at the time of registration, pesticide efficacy does not remain unregulated by the EPA. Pesticide registrants must generate efficacy data, balance that data with the proposed label instructions, and hold that data ready for EPA review as it may require. 40 C.F.R. § 158.640(b)(1). The EPA may review and require data if efficacy-related problems develop after initial registration. *See* 40 C.F.R. § 158.640(b) (EPA "reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration."). The EPA also will require submission of efficacy data if "a pattern of inaccurate, outdated, or ambiguous use directions is determined to be a major problem." 49 Fed. Reg. 37,960, 37,961 (Sept. 26, 1984). Additionally, FIFRA requires the reporting of any significant crop damage caused by the manufacturer's products, which includes reports of inefficacious products. *See* 40 C.F.R. § 159.184 (c)(5)(iv). This information may lead to revisions of a product's labeling to mitigate any further risk of crop damage. *See* 62 Fed. Reg. 49, 370, 49, 372 (1997). The EPA maintains the continuing responsibility to review crop damage reports, and the EPA may levy fines against pesticide manufacturers that fail to report such crop damage. *See* 7 U.S.C. § 136*l*. Section 136a(c)(5) did not waive regulation by EPA of efficacy issues, it merely changed the methods for that regulation.

Additionally, while Texas or any other state may not impose its own requirements for labeling, it can restrict or prohibit the sale or use of products that it determines are

inefficacious. Section 136v(a) of FIFRA provides that a "State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter." § 136v(a); *see also* TEX. AGRIC. CODE ANN. § 76.001, *et seq.* Congress granted states the ability to regulate efficacy issues. However, the express pre-emption clause in § 136v(b) precludes states from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging in addition to or different from those required" by FIFRA.

Therefore, the argument of the Petitioners and their Amici that a pesticide's efficacy is not regulated by EPA is clearly wrong. The EPA can examine the required efficacy data at any time and require changes in the label based on that data. The states can ban a pesticide from sale in that state but cannot by statute, regulation, or common law action, establish requirements regarding labeling of the product.

The lower court correctly concluded that FIFRA expressly pre-empted Petitioners' label-based claims. However, as demonstrated in the next section, the lower court could have also concluded that FIFRA pre-empts Petitioners' claims by implication because those state law claims conflict with the EPA's comprehensive regulatory regime governing pesticides.

B. FIFRA Pre-empts Petitioners' Claims By Implication

1. Despite The Existence Of FIFRA's Express Pre-emption, The Court Should Consider The Issue Of Implied Pre-emption.

Separate and distinct from the contours of express pre-emption is the doctrine of implied conflicts pre-emption. Pre-emption may be implied when congressional intent to pre-empt is implicitly contained in the structure and purpose of the statute. *FMC Corp. v. Holliday*, 498 U.S. 52, 56-57 (1990). The Court has found conflict pre-emption where state law "'under the circumstances of th[e] particular case . . . stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' — whether that 'obstacle' goes by the name of 'conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; ...interference' or the like." *Geier*, 529 U.S. at 873 (internal citations omitted). As a practical matter, no functional distinction exists between conflicts that "prevent or frustrate the accomplishment of a federal objective" and conflicts that make it impossible to "comply with both state and federal law" — the Supremacy Clause trumps and "nullifies" both forms of conflicting state law. *Id.* at 873.

Dow AgroSciences raised the issue of implied pre-emption in the courts below. Dow's Complaint for Declaratory Relief and Dow's First Amended Complaint for Declaratory Relief both asserted (in identical language) that Petitioner's state law claims were impliedly pre-empted by FIFRA's extensive regulatory regime:

> [Petitioners'] claims are also impliedly pre-empted by federal law because they (1) conflict with FIFRA's regulatory scheme and (2) directly

> conflict with the express authority given to registrants — such as Dow AgroSciences — to "distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency."

(Dow AgroSciences' Complaint for Declaratory Relief, at ¶ 45, JA 21; Dow AgroSciences' First Amended Complaint for Declaratory Relief, at ¶ 45, JA 203).

The court of appeals, however, did not conduct an independent analysis of implied pre-emption issues under FIFRA properly raised by Respondent because it found that Petitioners' causes of action were expressly pre-empted. Courts should, however, conduct an analysis of implied pre-emption issues, irrespective of whether the statute in question also contains an express pre-emption provision.

In *Freightliner Corp. v. Myrick*, this Court considered both express and implied pre-emption issues under the National Traffic and Motor Vehicle Safety Act of 1966 and its implementing provisions. 514 U.S. 280, 283 (1995). The respondents in *Freightliner* argued that implied pre-emption cannot exist when the statute in question contains an express pre-emption clause. This Court found this argument to be "without merit." *Id.* at 287. This Court specifically held that the existence of an express pre-emption provision in a statute does not eliminate the need for consideration of implied pre-emption issues where appropriate. *Id.* at 288-89 (noting that *Cipollone* does not establish a rule that an express preemption clause forecloses implied preemption); *see also Geier*, 529 U.S. 861, 872-74; *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352 (2001) (considering express and implied pre-emption under the Food, Drug and Cosmetic Act and the Medical

Device Amendments of 1976 and concluding "[t]o the extent respondent posits that anything other than our ordinary pre-emption principles apply under these circumstances, that contention must fail in light of our conclusion last Term in [*Geier*] that neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'") (quoting *Geier*) (internal citations omitted). For these reasons, the Court should examine whether FIFRA impliedly pre-empts Petitioners' causes of action. In this case, such an examination leads to the inescapable conclusion that FIFRA's intense regulatory regime governing the labeling and registration of pesticide products impliedly pre-empts state law claims such as those raised by the Petitioners.

2. Federal Regulations May Pre-empt Conflicting State Laws Even In The Absence Of Express Congressional Intent To Pre-empt, And Are Not Subject To A Presumption Against Pre-emption.

The Court has recognized that a federal statute "implicitly overrides state law either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively, or when state law is in actual conflict with federal law." *Freightliner*, 514 U.S. at 287. The Court has found implied conflict pre-emption in cases in which it is not possible for a private party to comply simultaneously with both state and federal requirements. *See English v. Gen Elec. Co.*, 496 U.S. 73; 78-79 (1990). The Court has also found implied conflict pre-emption where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Congressional intent to displace state law can be inferred where a "scheme of federal regulation may be so pervasive as to make reasonable the

inference that Congress left no room for the States to supplement it." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). This can occur either where an act of Congress

> 'may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject,' or because 'the object sought to be obtained by federal law and the character of the obligations imposed by it may reveal the same purpose.'

Fidelity Fed. Sav. and Loan Assoc. v. de la Cuesta, 458 U.S. 141, 153 (1982) (quoting *Santa Fe Elevator*).

Express Congressional intent is not a factor under implied conflict pre-emption analysis. "A pre-emptive regulation's force does not depend on express congressional authorization to displace state law . . ." *de la Cuesta*, 458 U.S. at 154. The phrase "Laws of the United States" in the Supremacy Clause is broad enough to encompass "federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization. . . ." *City of New York v. FCC*, 486 U.S. 57, 63 (1988). A federal agency acting within the scope of the authority Congress has granted it may pre-empt state regulations and displace state or local laws that would otherwise be consistent with federal law. *Id. See also La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 368-69 (1986). In a situation where the pre-emption analysis centers on the extent to which federal regulations can usurp state laws, the Court has advised that:

> . . . [T]he inquiry becomes whether the federal agency has properly exercised it own delegated authority rather than simply whether Congress has

> properly exercised the legislative power. Thus, we have emphasized that in a situation where state law is claimed to be pre-empted by federal regulation, a "narrow focus on Congress' intent to supersede state law [is] misdirected," for [a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law." . . . The statutorily authorized regulations of an agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof. . . . It has long been recognized that many of the responsibilities conferred on federal agencies involve a broad grant of authority to reconcile conflicting policies.

City of New York v. FCC, 486 U.S. at 64 (internal citations omitted). Thus, conflict pre-emption differs from express pre-emption because the former depends on an identification of actual conflict, whereas the latter depends on an express congressional statement reflecting an intent to pre-empt. *Geier*, 529 U.S. at 884.

No presumption against pre-emption exists under implied conflict pre-emption analysis. The Court has instructed that "[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that federal law must prevail." *Free v. Bland*, 369 U.S. 663, 666 (1962); *see also Felder v. Casey*, 487 U.S. 131, 138 (1988) ("any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield."); *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir.), *cert. denied*, 525 U.S. 1018 (1998) ("When considering implied [conflict] pre-emption, no presumption exists against pre-emption.").

In the present case, Congress enacted FIFRA to create a comprehensive regulatory scheme aimed at controlling the registration, use, sale, and labeling of pesticides. *See Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). FIFRA's express pre-emption clause is automatic, unconditional, and self-executing. FIFRA's over-arching purposes and its comprehensive regulatory structure, and the EPA's implementation of it, compels federal pre-emption separately and independently from § 136v(b)'s express pre-emptive command.

a. FIFRA's Registration Requirements Create A Pervasive Regulatory Scheme.

All pesticides sold or distributed in the United States must be registered by the Administrator of the EPA. 7 U.S.C. § 136a(a). "An application for new registration must be approved by the EPA before the product may be legally distributed or sold. . . ." 40 C.F.R. § 152.42. The registration process for pesticides is painstakingly meticulous. A list of the required contents for an application for registration can be found at 40 C.F.R. § 152.50. The applicant must file a statement which includes the complete formula of the pesticide. 7 U.S.C. § 136a(c)(1)(D). The EPA then undertakes a comprehensive review of all pertinent data and determines whether it is sufficient to satisfy the requirements of FIFRA. 40 C.F.R. § 158.80(a). The EPA's data requirements for registration are designed to "specify the types and minimum amounts of data and information the EPA requires in order to make regulatory judgments about the various kinds of pesticide products under the criteria set forth in FIFRA sections 3(c)(5)(C) and (D) and 3(c)(7). 40 C.F.R. § 158.20(b)(1). The data requirements for pesticide registration specified in this section of the regulations "pertain to product chemistry, residue chemistry, environmental fate, toxicology, reentry protection, aerial drift evaluation,

wildlife and aquatic organisms, plant protection, nontarget insects, product performance, and biochemical and microbial pesticides." 40 C.F.R. § 158.20(c). The "data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide." 40 C.F.R. § 158.202(a).

The EPA may register a pesticide only after the Administrator weighs the risks involved with the use of the product and determines that the product generally does not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D); 7 U.S.C. § 136(a)(c)(7). Congress has defined the term "environment" to include "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these." 7 U.S.C. § 136(j). Congress has also defined the term "unreasonable adverse effects on the environment," in relevant part, as follows:

> The term "unreasonable effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food consistent with the standard under section 346a of Title 21.

7 U.S.C. § 136(bb).

In other words, the EPA may register a pesticide only after it determines, at a minimum that (1) it possesses all data necessary to make the determinations required by FIFRA with respect to the pesticide product, including data needed to characterize any incremental risk that would result from

approval of the application; and (2) approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment. 40 C.F.R. § 152.113.

The EPA's decision to register a pesticide comes only after the EPA has convinced itself that product in question does not pose an unreasonable risk of harm. Thus, by virtue of the fact that the Administrator has registered a pesticide, the EPA necessarily has concluded that the product poses no unreasonable risk of harm to the environment (including man) when properly applied, and that its packaging, testing, and accompanying labeling are reasonable and appropriate when the product is "used in accordance with widespread and commonly recognized practice." 7 U.S.C. § 136a(c)(5)(D).

This comprehensive regulatory regime reflects the fact that Congress has expressly authorized the EPA to obtain the information it needs to reach an informed decision about whether a particular pesticide should be registered. The EPA will not register any pesticide until it "has determined that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment." 40 C.F.R. § 115.112(e). Additionally, as set forth below, the EPA will not register a pesticide until it has also determined that the "product is not misbranded as that term is defined in FIFRA[3] . . . and its labeling and packaging comply with the applicable requirements of the Act [and its implementing regulations]" 40 C.F.R. § 152.112(f). Taken together, the registration and labeling requirements authorized by Congress and implemented by the EPA constitute clear evidence of an overarching federal role in regulating pesticides.

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3. *See* 7 U.S.C. § 136(q).

b. FIFRA's Labeling Requirements Create A Pervasive Regulatory Scheme.

Because of the crucial role that product labeling plays in the registration process, Congress has equipped the EPA with substantial power to heavily regulate the design and the content of the label for a registered pesticide. 40 C.F.R. § 156.10. Congress has defined the term "label" as "the written, printed or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." 7 U.S.C. § 136(p)(1). The term "labeling" is more broadly defined as "all labels and other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device . . ." 7 U.S.C. § 136(p)(2). These definitions evidence a Congressional intent to regulate virtually any written or printed explanatory materials that accompany the sale or distribution of a pesticide, as well as information incorporated into the label by reference.

Generally, every pesticide label must clearly and prominently show the following information: (1) the name, brand, or trademark under which the product is sold; (2) the name and address of the producer, registrant, or person for whom produced; (3) the net contents of the pesticide; (4) the product registration number; (5) the producing establishment; (6) an ingredient statement; (7) hazard and precautionary statements for human, domestic animal, and environmental hazards; (8) the directions for proper use of the pesticide; and (9) the use classifications of the pesticide. 40 C.F.R. § 156.10(a)(1)(i)-(ix). All required labeling information "must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the

labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 40 C.F.R. § 156.10(2)(i).

EPA regulations also set forth stringent rules prohibiting the use of false or misleading labeling statements. A pesticide is misbranded if "its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims." 40 C.F.R. § 156.10(a)(5). Examples of statements or representations that constitute misbranding include false or misleading statements (1) about the composition of the product; (2) about the effectiveness of the product; (3) about the value of the product "for purposes other than as a pesticide or device;" (4) that improperly compare the product with other pesticides or devices; (5) obscuring the identification of active ingredients; and (6) implying government endorsement. 40 C.F.R. § 156.10(a)(5). EPA regulations also contain specific requirements concerning the content, placement, type size, and prominence of warnings and precautionary statements. 40 C.F.R. § 156.10(a)(vii); (2)(i)-(ii).

Perhaps the most fundamental aspect of a pesticide's labeling is the product's "Directions for Use." *See generally* 40 C.F.R. § 156.10(i). Pesticide labels must contain specific and detailed warnings, instructions, and directions for use, under the heading of "Directions for Use." 40 C.F.R. § 156.10(i)(2). EPA regulations require that the directions "must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects in the environment." 40 C.F.R. § 156.10(i)(1)(i). Furthermore, EPA regulations mandate that the directions for use require (1) the statement of use classification; (2) the

statement "it is a violation of Federal law to use this product in a manner inconsistent with its labeling;" (3) the sites of application (e.g. the crops, animals, areas, or objects to be treated); (4) the target pest(s) associated with each site; (5) the dosage rate associated with each pest; (6) the method of application; (7) the frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment; (8) worker protection statements; (9) specific directions concerning the storage and disposal of the pesticide and its container; and (10) any limitations or restrictions on use required to prevent unreasonable adverse effects. 40 C.F.R. § 156.10(i). FIFRA and its regulations require that the label "appear on or be securely attached to the immediate container of the pesticide product"; or, "[i]f the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is part of the package customarily distributed or sold." 40 C.F.R. § 156.10(a)(4)(i).

It cannot be reasonably disputed that Congress intended for federal rules and regulations to feature prominently, if not exclusively, in the registration and labeling requirements of pesticides. Having established federal supremacy in this area, this Court must not allow courts to impose civil liability under state law in a manner inconsistent with this national, uniform regulatory regime.

3. Compliance With FIFRA's Pervasive Registration And Labeling Requirements Provides A Sufficient Basis For Finding Implied Conflict Pre-emption.

Once the EPA registers the product and approves the label "[a] registrant may distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency." 40 C.F.R. § 152.130(a). It is a statutory violation, punishable, by both civil and criminal penalties, to use a registered product in a manner inconsistent with its labeling. 40 C.F.R. § 156.10(i)(2)(ii). When EPA registers a pesticide, the EPA has made a determination that the product adequately and sufficiently conveys all legally required warnings, precautions, and instructions for use. This determination should foreclose state law causes of action such as those alleged by the Petitioners in this case. As the Court explained in *Geier*, implied conflict pre-emption principles arising from regulatory action by federal agencies may provide additional bases for federal pre-emption, compel pre-emption more broadly than the terms of an express pre-emption provision, and may trump a statutory savings clause. This straightforward and independent analysis affirmatively negates Petitioners' claims and, through an ordinary conflicts pre-emption analysis, provides independent, additional, and broader reasons for finding pre-emption. Thus, for a jury to impose damages against the manufacturer or distributor of an EPA-approved and registered pesticide, the jury must find that the EPA (1) was simply wrong in deciding that the product's instructions for use were in fact adequate to protect public health and the environment; and (2) was also wrong in deciding that the product's warnings and precautions were in fact adequate to protect public health and the environment. This simply should not be the case. "[A] jury determination, via a state common

[law] tort judgment, that a pesticide's labeling is inadequate results in a direct conflict with the EPA's determination that the labeling is adequate to protect against health risks." *Olin*, 313 F.3d at 1311. In other words, a jury should not be permitted to conduct an *ex post facto* review of a product's composition, risks, and benefits where the EPA has already engaged in an identical exercise and determined that the product is safe if used in accordance with its label.

Federal regulations have the same pre-emptive effect as federal statutes. *Id.* Under implied conflict pre-emption analysis, the conflict between regulations promulgated by a federal agency and state law "does not evaporate because the . . . regulation simply permits, but does not compel" the conduct in question. *Id.* at 155. Accordingly, "[a] state cannot impose common law damages on individuals for doing what a federal act or regulation 'authorized them to do.'" *Griffith v. General Motors Corp.*, 303 F.3d 1276, 1281 (11th Cir. 2002), *cert. denied*, 123 S. Ct. 1953 (2003) (quoting *Taylor v. General Motors Corp.*, 875 F.2d 816, 827 (11th Cir. 1989) (quoting, in turn, *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 318-20 (1981)). Because the EPA's regulations expressly permit a registrant to distribute or sell its product as approved by the EPA, a jury verdict imposing damages for doing what federal regulations expressly permit is forbidden by the Supremacy Clause. "[T]he Supremacy Clause secures federal rights by according them priority whenever they come in conflict with state law." *Rondout Elec., Inc. v. NYS Dep't of Labor*, 335 F.3d 162, 166 (2d Cir. 2003) (internal citations omitted).

Petitioners cannot challenge these determinations and decisions made by the EPA after appropriate investigation and review. "To hold otherwise would be to allow state courts to sit, in effect, as super-EPA review boards that could

question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations." *Welchert*, 59 F.3d at 73. "'[I]t is for the EPA administrator, not a jury, to determine whether labeling and packaging information is incomplete or inaccurate, and if so, what label changes, if any, should be made . . . We think FIFRA leaves states with no authority to police manufacturers' compliance with federal procedures.'" *Pure-Gro*, 54 F.3d at 561 (quoting *Papas*, 985 F.2d at 519).

In fact, subjecting registrants to multiple and potentially inconsistent state tort liability standards could well undermine effective enforcement of FIFRA:

> In particular, we are troubled that an applicant's disclosures under FIFRA, although not challenged by the EPA (the very agency empowered by Congress to enforce FIFRA), may be judged illegal under state law. Such an approach would force FIFRA applicants to ensure that their disclosures to the EPA would satisfy not only the standards imposed by that agency under federal law, but also the potentially heterogeneous standards propounded by each of the 50 states. Such a holding would in turn motivate potential applicants under FIFRA to "submit a deluge of information that the [EPA] neither wants not needs, resulting in additional burdens on the [EPA's] evaluation of an application." This outcome would needlessly drain the EPA of its limited resources, thereby detracting from its ability to efficiently enforce FIFRA.

Nathan Kimmel, 275 F.3d at 1207 (quoting *Buckman*, 531 U.S. at 351).

For these reasons, this Court should rule that the imposition of tort liability under state law for the sale or distribution of registered pesticides must give way to FIFRA's comprehensive regulatory scheme because imposing liability under these circumstances would deal a devastating blow to the EPA's congressional mandate to enact uniform national rules and regulations governing the safety of pesticides on public health and the environment.

CONCLUSION

Where federal law and state law conflict, federal law prevails. Uniformity in pesticide labels is a key component of the FIFRA scheme. Uniformity is difficult to be achieved if federally-approved labels may be challenged in different courts around the country. One court decision could require certain language on the label, and another court could require different language for the same label, making uniformity impossible.

In order to maintain uniformity in pesticide labels, this Court should follow it analysis in *Cipollone* and find that all of the Petitioners' claims are pre-empted under FIFRA. The Court should additionally find that all of the Petitioners' claims are pre-empted under implied pre-emption.

Respectfully submitted,

JAMES L. MOORE*
GLEN SHU
MATTHEW W. CALIGUR
BAKER & HOSTETLER LLP
1000 Louisiana, Suite 2000
Houston, TX 77002
(713) 751-1600

PATRICK LYSAUGHT
BAKER STERCHI COWDEN
& RICE, LLC
Crown Center, Suite 500
2400 Pershing Road
Kansas City, MO 64108-2504
(816) 471-2121

Attorneys for Amicus Curiae

* *Counsel of Record*