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In Defense of FIFRA Preemption of Failure to Warn Claims

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Suppose you own a company that manufactures pesticides. In compliance with the Federal Insecticide, Fungicide, and Rodenticide Act[1] (FIFRA) and the regulations promulgated thereunder, you take the detailed steps to have the pesticide and the pesticide label approved by the Environmental Protection Agency (EPA). After approval, your company sends the pesticide to the marketplace. Imagine your surprise when, after having your pesticide and label approved under FIFRA, an action is brought against your company claiming that the label failed to warn a user of an alleged risk. Was the EPA approval of the label for naught? Does not a federal law preempt state law when Congress has chosen to occupy the field? And has not Congress, through FIFRA, chosen to occupy the field?[2]

This is the issue faced by various courts considering failure to warn claims against pesticide and chemical manufacturers regulated under FIFRA. While a great majority of the courts have sided with defendant-manufacturers in these cases, some courts have found and some commentators assert that FIFRA does not preempt state common law failure to warn claims based on the EPA-approved labels. This Note seeks to defend the approach taken by the great majority of courts in finding FIFRA preemption of failure to warn claims. Part I will present an overview of FIFRA and preemption doctrine. Part II will discuss the cases interpreting FIFRA's preemption clauses. Part III explains that FIFRA's preemption clause should be interpreted to preempt state common law failure to warn actions because that approach advances the goals of FIFRA, is in line with Supreme Court precedent,

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[1] Pub. L. No. 80-104, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y (1994)).

[2] For a competing tale of woe told from the plaintiff's perspective, *see* R. David Allnut, Comment, *FIFRA Preemption of State Common Law Claims After Cipollone v. Liggett Group, Inc.*, 68 WASH. L. REV. 859 (1993).

and leaves those who have been hurt by a pesticide approved under FIFRA with some remedy at common law. Finally, Part IV will examine the most recent case in which the Supreme Court interpreted a preemption statute and explain why its holding is not applicable to FIFRA failure to warn claims.

I. FIFRA: THE LAW AND ITS HISTORY

Congress passed FIFRA in 1947 to replace the Insecticide Act of 1910.[3] The 1947 Act provided for thorough and comprehensive regulation of pesticides. In addition to expanding the scope of the Insecticide Act, which sought to prevent deceptively mislabeled and watered-down pesticides in the flow of commerce, FIFRA was passed to address problems with pesticides that various state acts, including the Uniform Insecticide, Fungicide, and Rodenticide Act, had attempted to address, namely the prevention of harm to humans from pesticides.[4] Under the 1947 Act, all pesticides in interstate commerce had to be registered with the Department of Agriculture.[5]

Congress greatly amended FIFRA in 1972.[6] Changes were made in pursuit of the goal of "protect[ing] man and his environment,"[7] and administration of FIFRA was removed from the Department of Agriculture and placed in the hands of the EPA.[8] The 1972 Amendments also expanded the statute's reach to include intrastate sale and use of pesticides.[9] Further, less comprehensive amendments were made in 1988 and in 1991.[10]

Section 136v is of particular importance to the discussion of

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[3] The Insecticide Act of 1910, ch. 191, 36 Stat. 331(1910), *repealed by* The Federal Insecticide, Fungicide, Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163, (codified as amended at 7 U.S.C. §§ 136-136y (1994).

[4] William T. Smith, III & Kathryn M. Coonrod, *Cippolone's Effect on FIFRA Preemption*, 61 UMKC L. REV. 489, 490 (1991).

[5] Timothy J. Kuester, Comment, *FIFRA as an Affirmative Defense: Pre-emption of Common-Law Tort Claims of Inadequate Labeling*, 40 U. KAN. L. REV. 1119, 1122 (1992).

[6] Pub. L. No. 92-516, 86 Stat. 973 (1972) (codified at 7 U.S.C. §§ 136 to 136y).

[7] *See* S.REP. NO. 92-838, at 3 (1972). *reprinted in* 1972 U.S.C.C.A.N. 3993, 3999.

[8] "The EPA was created in 1970 and was only two years old when it received statutory authority to enforce the regulations contained in FIFRA." Brian M. Brown, Note, *Federal Preemption of State Tort Law Failure to Warn Claims by FIFRA: Injury Without Relief?*, 4 S.C. ENVTL. L.J. 147, 149 n.14 (1995).

[9] *See* S.REP. NO. 92-838, *supra* at note 7, at 3994.

[10] Pub. L. No. 100-532, 102 Stat. 2655 (1988) (codified as amended at scattered sections of 7 U.S.C.).

FIFRA preemption. Section 136v(a) grants states the power to "regulate the sale or use of any federally registered pesticide or device in the State," but with the limitation that the states cannot regulate such sale or use in contradiction of FIFRA.[11] Section 136v(b), which bears the heading "Uniformity," makes clear that, notwithstanding the States' power authorized in section 136v(a), "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."[12] Clearly, then, Congress has disallowed any state statutory enactment that purports to regulate labeling or packaging on pesticides. The question remains, however, what effect FIFRA preemption has on state common law tort actions that effectively do the same.

A. Pesticide and Pesticide Label Review Under FIFRA

Both FIFRA and the EPA regulations promulgated pursuant thereto have brought extensive control to pesticide manufacturing and labeling.[13] The process of registration begins with the pesticide manufacturer's application to the EPA.[14] In addition to the application, the applicant may be required to submit detailed descriptions of tests performed as required under the EPA's regulations, and the results of those tests.[15] The application must also include a copy of the label the manufacturer intends to place on the pesticide container.[16] The EPA reviews the label for, among other things, the adequacy of warnings and precautions provided, and appropriate directions for use.[17] Warnings and precautionary statements are subject to regulations dictating the content, type size, color, placement, and prominence of the writing on the label.[18] If the pesticide poses a risk to human or animal life, the warning should identify with particularity the hazard, how one may be exposed to the hazard, and how the hazard may be avoided.[19] Furthermore, directions for use must be written so that an average person using

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[11] 7 U.S.C. § 136v(a) (1994).

[12] *Id.* § 136v(b).

[13] Judi Abbott Curry et al., *Federal Preemption of Pesticide Labeling Claims*, 10 ST. JOHN'S J. LEGAL COMMENT. 325, 328 (1995).

[14] 7 U.S.C. § 136(c) (1994).

[15] *Id.* § 136a(c)(1)(F).

[16] *Id.* § 136a(c)(1)(C).

[17] 40 C.F.R. § 156.10(a)(1) (1996).

[18] *Id.* § 156.10(h).

[19] *Id.* § 156.10(h)(2)(i)(A).

the pesticide can read and understand the directions.[20]

In general, specific language is not required for warnings and precaution statements. Instead, the EPA's regulations supply general guidelines and typical warnings for different categories of pesticides to aid the pesticide manufacturer in writing its own warning tailored to the specific hazards posed by its product.[21] This makes sense in the realm of pesticide regulation because EPA could not promulgate one warning label that would be effective for every pesticide, nor could the EPA reasonably be expected to create such a warning label. Thus, allowing the manufacturer to submit a warning label for EPA review and approval is the most sensible and efficient way to promote the goals of FIFRA.

B. Preemption

The Supremacy Clause of the United States 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."[22] Modern interpretation of this Constitutional clause has led to two possible ways a federal statute can be found to preempt state or local law: express or implied preemption. In express preemption, the court will look to the statutory language to determine if it specifically states that it preempts an area of law.[23] Implied preemption may arise when a statute is so thorough and comprehensive that it is clear Congress intended to "occupy the field," or where state law directly conflicts with federal law.[24]

II. CASES ADDRESSING FIFRA AND PREEMPTION OF FAILURE TO WARN

The controversy surrounding FIFRA preemption has only surfaced relatively recently. The first case to address the question whether FIFRA preempted a state common law failure to warn claim answered the question in the negative. In *Ferebee v. Chevron Chemical Co.*,[25] an

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[20] 7 U.S.C. § 136(q)(1)(E); 40 C.F.R. § 156.10(i)(1)(i).

[21] *See* 40 C.F.R. §§ 156.10(a)-(j) (1996).

[22] U.S. CONST. art. VI, cl. 2.

[23] Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).

[24] *Id. See* 7 U.S.C. § 136v (1994); text at nn. 11 & 12.

[25] 736 F.2d 1529 (D.C. Cir. 1984).

agricultural worker in the United States Department of Agriculture contended that he developed pulmonary fibrosis as a result of skin exposure to the herbicide paraquat.[26] Paraquat was registered with the EPA, and the label involved was approved by the EPA under FIFRA.[27] The label warned of the possibility of severe skin irritation upon exposure to paraquat, as well as the risk that prolonged exposure could result in skin absorption of paraquat.[28] The trial court found in favor of the plaintiff based on Chevron's failure to warn the plaintiff of the risk that prolonged exposure to paraquat could result in chronic lung disease.[29]

On appeal before the United States Court of Appeals for the District of Columbia, Chevron contended that FIFRA preempted the plaintiff's failure to warn cause of action.[30] Chevron argued that the EPA's approval of the label, coupled with FIFRA's preemption clause, prevented a state court from finding otherwise.

In rejecting Chevron's arguments, the court found FIFRA served a regulatory function, while state common law tort actions served the different function of compensating injured individuals.[31] The court concluded that, simply because the EPA approved a label using a cost-benefit analysis does not mean that a state court cannot compensate an injured party if the label does not warn of a significant risk.[32] Thus, in the absence of federal preemption, a state court is not bound by the conclusions of the EPA.

The court found no express preemption in section 136v(b) of FIFRA. Congress had specifically expressed its intent with regard to common law preemption in other preemption statutes, but failed to do so here.[33] Applying implied preemption analysis, the court found that state common law did not conflict with FIFRA because a pesticide manufacturer has what has been termed a "choice of reaction:"[34] Either do nothing and accept the liability when state courts find liability, or re-apply to the EPA to have the label changed to incorporate the warning

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[26] *Id.* at 1531-32.

[27] *Id.* at 1539.

[28] *Id.* at 1536-37.

[29] *Id.* at 1532.

[30] Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1539 (D.C. Cir. 1984).

[31] *Id.* at 1540.

[32] *Id.*

[33] *Id.* at 1542.

[34] Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 959 F.2d 158, 162 (10th Cir. 1992).

the court found to be lacking.[35] According to the court, because the manufacturer has the option of not changing the label, there is no conflict between FIFRA's labeling requirements and state common law tort actions, and therefore there is no implied preemption under FIFRA.

Later circuit court decisions addressing FIFRA preemption of state common law failure to warn actions concluded differently than the *Ferebee* court. *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*,[36] for example, involved a business that acquired property formerly occupied by a business where wooden fence posts were treated with a chemical known as Dowicide-7.[37] Several employees of Arkansas-Platte were poisoned by pentachlorophenol vapors from the site, and the company sued the manufacturer and distributor of Dowicide-7 on a negligent failure to warn theory.[38] The defendants made a motion for summary judgment based on FIFRA preemption, but the motion was denied. On interlocutory appeal, however, the Court of Appeals for the Tenth Circuit reversed, holding that FIFRA implicitly preempted plaintiff's failure to warn theory.[39]

The court looked at the language of section 136v(b) and concluded that it expressly preempted statutory enactments of state law pertaining to product labeling. With regard to common law tort damage awards, the court reasoned that such court pronouncements would directly conflict with FIFRA.[40] Thus, FIFRA implicitly preempted such actions.

The *Arkansas-Platte* court found some support for its position in the Supreme Court's decision in *Wisconsin Public Intervenor v. Mortier*.[41] In *Mortier*, the Court addressed whether FIFRA preempted local regulation of pesticide use. Although the Court answered this question in the negative,[42] more important to the *Arkansas-Platte* decision was the implication throughout the *Mortier* opinion that while local *use* regulations were not preempted, any regulation of pesticide *labeling* was preempted under FIFRA.[43] Although the Court's decision

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[35] *Id.*

[36] 959 F.2d 158 (10th Cir 1992), *vacated and remanded sub nom*, Arkansas-Platte & Gulf Partnership v. Dow Chem. Co., 506 U.S. 910 (1992).

[37] *Id.* at 159.

[38] *Id.* at 159.

[39] *Id.* at 159.

[40] *Id.* at 161.

[41] 501 U.S. 597 (1991).

[42] *Id.* at 606-14.

[43] "[Section 136v(b)] would be pure surplusage if Congress had intended to occupy the entire field of pesticide regulation." *Id.* at 613; "As we have also made plain, local use permit regulations–unlike labeling or certification–do not fall within an area that FIFRA's 'program'

in *Mortier* did not directly address whether FIFRA preempts state statutory or common law and its implications are only dicta, the decision indicates that the Court may find that FIFRA preempts state common law failure to warn claims.

The Tenth Circuit in the *Arkansas-Platte* decision did not accept the "choice of reaction" analysis formulated by the court in *Ferebee*.[44] The decision concluded that the choice was illusory, as logical business considerations would clearly warrant a label change.[45] Thus, the choice is inconsistent with FIFRA's mandate that state law addressing labeling and packaging requirements be preempted.

A. Turning Point: The *Cipollone* Decision

In *Cippollone v. Liggett Group, Inc.*,[46] the Supreme Court specifically addressed whether federal cigarette laws preempted state tort law damage claims. The federal laws at issue in *Cippolone* were the Federal Cigarette Labeling and Advertising Act of 1965[47] and the Public Health Cigarette Smoking Act of 1969.[48] The trial court found that neither Act preempted state law failure to warn actions.[49] On interlocutory appeal, the Third Circuit Court of Appeals reversed.[50] On remand, a jury verdict found the failure to warn claim preempted, but predicated its decision for the plaintiff on the defendant's breach of express warranties and failure to warn its customers of the health risks of smoking prior to the 1966 effective date of the legislation.[51] The Third Circuit affirmed the decision on appeal, and the Supreme Court granted certiorari.[52]

In addressing the question whether the federal statutes preempted state common law actions, the Court did not engage in an implied preemption analysis. Instead, it limited its inquiry to an express preemption analysis, explaining that where Congress had addressed the

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preempts or even plainly addresses." *Id.* at 615.

[44] Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 959 F.2d 158, 162-3 (1992); Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1541 (D.C. Cir. 1984).

[45] *Arkansas Platte*, 959 F.2d at 162-63.

[46] 505 U.S. 502 (1992).

[47] Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-41 (1965), *amended by* The Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1331-41 (1994).

[48] 15 U.S.C. §§ 1331-41 (1994).

[49] *Cipollone*, 505 U.S. at 510.

[50] *Id.* at 511.

[51] *Id.* at 512.

[52] *Id.*

preemption issue in a statutory provision, the Court should give effect to only that expressed in the preemption provision.[53] The 1965 Act provided that, "[n]o statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package."[54] The 1969 Act provided that, "[n]o 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 provisions of this Chapter."[55]

The Court determined that the 1965 Act fell short of preempting the petitioner's state tort law damage claims because the language used showed that Congress was not attempting to preempt the entire field, and because there is a presumption against preemption where Congress attempts to usurp those powers, i.e., the police powers, usually reserved to the states.[56] As to the 1969 Act, the Court concluded differently. The amendments made in the 1969 Act convinced the Court that Congress now intended to preempt the field, including state statutes as well as state common law doctrine.[57] The question then addressed was whether the claims at trial were preempted by the 1969 Act. Some were found to be preempted, including the failure to warn claim, while others simply were not reached by the preemption provisions and thus survived.[58]

B. The Effect of *Cipollone* on FIFRA Preemption Cases

Before *Cipollone* was decided in 1992, the courts were equally split as to whether FIFRA preempted state common law failure to warn actions.[59] After *Cipollone*, however, the overwhelming majority of courts have found that FIFRA does indeed preempt such actions.[60]

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[53] *Id.* at 517.

[54] 15 U.S.C. §§ 1334(a) (1965), *amended by* the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1331-40 (1994). Section 1333 sets forth requirements with regard to warnings, packaging, advertisement and billboards.

[55] 15 U.S.C. §§ 1334(b) (1994).

[56] Cipollone v. Liggett Group, Inc., 505 U.S. 502, 518-20 (1992).

[57] *Id.* at 520-24.

[58] *Id.* at 524-30.

[59] Smith & Coonrod, *supra* note 4, at 499.

[60] *Id.* at 502.

III. JUSTIFYING FIFRA PREEMPTION

Though the Supreme Court spoke authoritatively in *Cipollone*, some feel that the conclusions drawn in that case do not necessarily apply to a FIFRA preemption case. The following is a discussion of the arguments set forth against FIFRA preemption in such cases, and a brief rebuttal on each point.

In arguing that *Cipollone* can be distinguished from a FIFRA preemption case, opponents of FIFRA preemption have latched on to the differences in language between section 5 of the 1969 Act and section 136v(b) of FIFRA. Whereas the 1969 Act's language allows no "requirements or prohibitions . . . imposed under State law,"[61] FIFRA's preemptive language is limited to "requirements" by a "State."[62] Thus, opponents of FIFRA have concluded that the two statutes are not analogous, and the reach of FIFRA must be less than that of the 1969 Act.[63]

The fact that the two statutes are not exactly alike must be conceded. However, to conclude that FIFRA has a lesser preemptive reach than the 1969 Act one must equate the words "prohibitions" and "law" with the words "state common law tort actions," and the omissions of these words should not be grounds for a finding that the preemptive effect is materially different. The *Cipollone* decision demands that the FIFRA preemption clause be analyzed under the test articulated by the court: Where there exists in a statute a preemption clause, a court should not engage in an implied preemption analysis, but should focus on the express intent of Congress in the preemptive clause to establish the extent of preemption.[64] Thus, instead of comparing the FIFRA preemption statute to the statute at issue in *Cippolone*, the FIFRA preemption provision itself must be examined to determine what Congress intended to preempt.

The Court in *Cipollone* recognized that regulation could be exerted just as effectively through an award of damages as through positive state enactments, and thus no distinction should be found between the two.[65] This is true because the underlying premise of a failure to warn claim is

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[61] 15 U.S.C. §§ 1334(b) (1994).

[62] 7 U.S.C. § 136v(b) (1994).

[63] *See* Brown, *supra* note 8, at 164-65; Allnut, *supra* note 2, at 875; Sandi L. Pellikaan, *FIFRA Preemption of Common-Law Tort Claims After Cipollone*, 25 ENVTL. L. 531, 538 (1995).

[64] Cipollone v. Liggettt Group, Inc., 505 U.S. 502, 517 (1992).

[65] *Id.* at 521.

that additional warnings should have been provided to the consumer.[66] Thus, any state common law failure to warn action must conflict with FIFRA's preemption clause just as a state statute would. It necessarily follows that any common law failure to warn action results in "requirements" by a "State" that conflict with those under FIFRA, and are preempted by section 136v(b).

It is also clear from Congress' decision to title the preemption section "Uniformity" that the goal of Congress was to create a single, comprehensive regulatory scheme for all pesticide manufacturers rather than a patchwork of state-enacted schemes in addition to the federal law.[67] Furthermore, as shown previously in the discussion of the *Mortier* case, the Supreme Court has implied that FIFRA clearly preempts state common law failure to warn actions based on alleged improper labeling and packaging.[68]

Opponents also argue that the "choice of reaction" analysis promoted by *Ferebee* should be the preferred analysis.[69] That choice is simply nonexistent. The Supreme Court considered and rejected this analysis in the context of a state nuisance challenge to a paper mill's emission of pollutants into Lake Champlain in *International Paper Co. v. Ouellette*.[70] The defendant paper mill in that case emitted pollutants pursuant to an EPA permit under the Clean Water Act (CWA). Should the plaintiffs recover, the Court reasoned, the defendant would have to, "at a minimum . . . change its methods of doing business and controlling pollution to avoid the threat of ongoing liability."[71] The same must be true under FIFRA, where good business judgment would compel a pesticide manufacturer after losing a state failure to warn action to re-petition the EPA for a change in its labeling. One court has compared this so-called choice in the choice of reaction analysis to "the free choice of coming up for air after being underwater."[72] Considering the Supreme Court's rejection of the choice of reaction analysis, then, it should be clear that the analysis can no longer validate state common law actions in conflict with FIFRA section 132v(b).

Those who oppose FIFRA preemption strenuously argue that

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[66] Caroline E. Boeh, Note, *Cipollone v. Liggett Group, Inc.: One Step Closer to Exterminating the FIFRA Preemption Controversy*, 81 KY. L.J. 749, 776 (1992/1993).

[67] *See* Kuester, *supra* note 5, at 1136.

[68] *See supra* notes 41-3 and accompanying text.

[69] *See* Pellikaan, *supra* note 63, at 542.

[70] 479 U.S. 481 (1987).

[71] *Id.* at 495.

[72] Palmer v. Liggett Group, Inc., 825 F.2d 620, 627 (1st Cir. 1987).

Congress surely would not and did not intend to preempt state common law tort actions meant to compensate innocent victims of insufficient warnings on pesticide labels.[73] This, however, is by necessity Congress' intent by enacting a comprehensive regulatory program intended to bring uniformity to the area of pesticide labeling and packaging.[74] As discussed previously, Congress and the EPA together have created a formidable process whereby a pesticide and its label are subject to great scrutiny.[75] Congress must have concluded when it created this regulatory structure that the EPA should be the only assessor of the warnings needed on such products.[76] Otherwise, the idea of uniformity would be mere "surplusage."[77] State actions where liability is predicated on a failure to warn will be decided differently by different juries both within and outside a state, creating the very disjunctive and nonuniform law that prompted Congress to pass FIFRA.

Those opposing FIFRA preemption argue that allowing state common law failure to warn actions will not result in nonuniformity because under the regulations no uniform warning is required.[78] This argument, however, fails to recognize that pesticide manufacturers have little leeway under the regulations because they must follow the guidelines and model warnings, as well as warn of known dangers. It is of necessity that no uniform warning label is provided for under the regulations, since all pesticides are not alike and manufacturers must warn of the particular risk(s) their products present. This may result in two very similar pesticides having differently worded labels, but the substance of both will be the same. Thus, the pesticide labeling regulations are as uniform as possible given the wide scope of the regulations, and such uniformity is substantially the same as regulation

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[73] *See* Pellikaan, *supra* note 63, at 541-42.

[74] Papas v. Upjohn Co., 926 F.2d 1019, 1025 (11th Cir. 1991), *vacated and remanded sub nom*, Papas v. Zoecon Corp., 505 U.S. 1215 (1992).

[75] *See supra* notes 13-21 and accompanying text.

[76] *See* Kuester, *supra* note 5, at 1140 ("Congress envisioned a uniform scheme of consistent labeling requirements to be executed exclusively by the EPA."); James P. Herrington, *Local Regulation of Pesticide Use and State Failure to Warn Claims: What Does FIFRA Preempt?–Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), 11 TEMP. ENVTL. L. & TECH. J. 317, 336 ("[J]uries who are ill-equipped with the technical knowledge needed to weigh the benefits of safer products against the costs to pesticide manufacturers and American agriculture will be making determinations of the adequacy of labels.")

[77] Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 613 (1991).

[78] *See* Stephen D. Otero, Note, *The Case Against FIFRA Preemption: Reconciling Cipollone's Preemption Approach With Both the Supremacy Clause and Basic Notions of Federalism*, 36 WM. & MARY L. REV. 783, 832 (1995).

which provides a uniform warning for all products, such as the cigarette warning label required under section 1333 of the Public Health Cigarette Smoking Act of 1969.

Finally, it is important to note that FIFRA only preempts a specifically defined area of state common law: negligent failure to warn actions based on product labeling. Those who wish to pursue liability against a pesticide manufacturer may do so by claiming that the manufacturer should have given warnings apart from its label to the community of users,[79] or by basing liability on a design defect.[80] FIFRA section 136v does not preempt these causes of action, and a plaintiff seeking compensation may be able to collect on those grounds.

IV. MUDDYING THE WATERS: *MEDTRONIC V. LOHR*

Recently, the Supreme Court passed judgment in a case that could have important ramifications in the continuing controversy of whether FIFRA preempts failure to warn claims. That case, *Medtronic v. Lohr*,[81] arose when a pacemaker component manufactured by Medtronic allegedly failed and Lohr required emergency surgery to correct the heart problems that ensued.[82] The pacemaker component was regulated under the Medical Device Amendments of 1976 (MDA).[83] Lohr filed suit, putting forth strict liability and negligence claims, including negligence based on a failure to warn.[84] In response, Medtronic moved for summary judgment based on the preemption provisions contained in the MDA.[85] The District Court granted the motion and dismissed

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[79] *See* Burke v. Dow Chem. Co., 797 F. Supp 1128, 1140 (E.D.N.Y. 1992).

[80] *See* Kevin McElroy et al., *The Federal Insecticide, Fungicide, and Rodenticide Act: Preemption and Toxic Tort Law*, 2 FORDHAM ENVTL. L. REP. 29, 39-42 (1990).

[81] 116 S.Ct. 2240 (1996).

[82] *Id.* at 2248.

[83] The Medical Device Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 (1976), *amended by* The Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. §§ 301-305); *Medtronic*, 116 S.Ct. at 2246-48.

[84] *Medtronic*, 116 S. Ct. at 2248.

[85] *Id.* The preemption statute, 21 U.S.C. § 360k(a) (1994), provides as follows:

> (a) General rule
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> Except as provided in subsection (b) of this section, 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–
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (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

Lohr's complaint.[86] On appeal to the Court of Appeals for the 11th Circuit, the decision was reversed in part and affirmed in part. In particular, the Court of Appeals upheld the decision of the lower court insofar as the failure to warn claims were concerned. The court cited the extensive labeling regulations promulgated by the FDA as conclusive proof that any claims of insufficient labeling were preempted.[87]

A majority of the Supreme Court, however, came to a different conclusion. The Court unanimously held that the strict liability claim for design defect was not preempted by the MDA, but as to the negligence claims, including the failure to warn claim, the Court split 5-4 against preemption. The majority opinion, authored by Justice Stevens, first focused its attention on the review process established by the MDA and what that process requires of medical devices before they are brought to market.[88] Specifically, the Court noted that two exceptions, a grandfather provision which allows devices on the market before the MDA took effect to continue on the market without FDA approval,[89] and another provision which allows devices that are "substantially equivalent" to products already on the market to be sold after only an abbreviated review,[90] created a situation where only a small portion of the devices brought to market were required to go through the extended review provided for under the MDA.[91] The pacemaker component involved here was only subject to the abbreviated review, as it was substantially equivalent to devices already on the market.[92]

The preemption provision at issue, the Court noted, clearly preempted state statutory law. The question, however, was whether it preempted state common law. To answer this question, the Court looked to two guiding principles: First, states are sovereign entities, and Congress would not "cavalierly"[93] preempt state common law; and second, the Court must look to Congressional purpose of the statutory provision at issue to determine its meaning.[94]

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[86] *Medtronic*, 116 S. Ct. at 2249.

[87] *Id.*

[88] *Id.* at 2246-48.

[89] *Id.* at 2247; 21 U.S.C. § 360e(b)(1)(A) (1994).

[90] *Medtronic*, 116 S. Ct. at 2247; 21 U.S.C. § 360(k) (1994).

[91] *Medtronic*, 116 S. Ct. at 2246-48.

[92] *Id.* at 2248.

[93] *Id.* at 2250.

[94] *Id.*

Using these guiding principles, Stevens' opinion summarily rejected Medtronic's argument that all common law actions are preempted by the MDA.[95] This, in his view, could not have been the intent of Congress, for it precluded state courts from protecting consumers from injuries resulting from medical devices.[96] Such an interpretation of the preemption statute, Stevens opined, would 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."[97]

Furthermore, Stevens' opinion addressed the language of the preemption provision and found it, too, to be lacking a clear intent to preclude all common law causes of action. He specifically focused on the word "requirement" in the statutory language and noted it was a "singularly odd word"[98] to use if total preemption was the goal of Congress. Stevens distinguished *Cippolone*, and its holding that a provision preempting state "requirements" could also bar common law damages claims, on the basis of the limited effect of the statute in *Cippolone* as compared to the far greater effect total preemption under the MDA would have both on state sovereignty and the ability of plaintiffs like Lohr to have some remedy for their injuries.[99] In a footnote, Stevens further differentiated *Cippolone* by noting that the statute involved in *Cippolone* in itself preempted the claims, whereas the preemption statute at issue here relied on agency regulations to define the scope of preemption.[100]

Stevens, however, was only able to amass three justices in support of his preemption analysis. Whereas Stevens concluded that the preemption provision would rarely, if ever, preempt state common law,[101] Justice Breyer, writing in concurrence, was not willing to read the statute so restrictively. Justice Breyer offered this example to support his reasoning:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch

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[95] *Id.*
[96] Id.
[97] Medtronic v. Lohr, 116 S. Ct. at 2251.
[98] *Id.*
[99] *Id.* at 2251-52.
[100] *Id.* at 2252 n.9.
[101] *Id.* at 2259.

> wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" MDA regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state tort law action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)? The effects of the state agency regulation 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.[102]

This, however, is the import of the plurality decision, an "anomalous result"[103] that Justice Breyer concludes was not intended by Congress.

Justice Breyer also stated his belief that the language in the preemption statute at issue in *Cippolone* is sufficiently similar to the language used in the MDA preemption statute to conclude as the Court had in *Cippolone* that "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief."[104] Thus, in Justice Breyer's opinion, a state tort law action which imposed requirements on a medical device manufacturer would be preempted under the MDA if a similar state statute or regulation would be preempted.

Nevertheless, Justice Breyer concluded that the state law claims at issue were not preempted because the FDA had issued a regulation stating the state requirement must be "different from, or in addition to, the *specific* [federal] requirements"[105] under the MDA to be preempted. Since the state law claims, including the failure to warn claim, put forth by Lohr were not in conflict with "specific" laws or regulations of the

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[102] Medtronic v. Lohr, 116 S. Ct. 2240, 2259 (1996) (Breyer, J., concurring in part and concurring in the judgment).

[103] *Id.* at 2260 (Breyer, J., concurring in part and concurring in the judgment).

[104] *Id.* at 2259 (Breyer, J., concurring in part and concurring in the judgment) (citing Cipollone v. Liggett Group, 505 U.S. 505, 521 (1992) (plurality opinion) (internal quotation marks omitted)).

[105] *Id.* at 2261. (Breyer, J., concurring in part and concurring in the judgment) (citing 21 CFR § 808.1(d) (1996)).

MDA, Justice Breyer found no federal preemption.[106]

Justice O'Connor, joined by three other justices, concurred in the decision insofar as it held there was no preemption of the design defect claim, but dissented with regard to the negligence claims. The dissent found no merit in the plurality's position that the word "requirement" used in the preemption provision does not encompass state common law claims, and instead found the rationale of *Cippolone* controlling.[107] The dissent further found fault with both the plurality's and Justice Breyer's reliance on an agency regulation to interpret the statute when the statute is clear in its meaning.[108] Because the dissent refused to consult the regulations to interpret the preemption statute, it thus read the statute without the requirement imposed by the plurality and Justice Breyer that the federal requirement be specific in order to preempt any state requirement. The statute and its regulations are, in the dissent's view, sufficiently comprehensive to preempt the manufacturing and failure to warn claims put forth by Lohr.[109]

V. THE RAMIFICATIONS OF *MEDTRONIC V. LOHR*

There are several significant differences between the MDA and FIFRA preemption provisions that provide a basis for believing the Supreme Court, or any other court for that matter, might reach a different conclusion than that reached in *Medtronic* when addressing whether FIFRA preempts a failure to warn claim. The arguments put forth here were extracted from a recent decision, *Lewis v. American Cyanamid Co.*,[110] which considered *Medtronic's* effect on FIFRA preemption of failure to warn claims and concluded such claims were still preempted.[111]

First, the plurality opinion in *Medtronic* placed a great deal of emphasis on the particular ease with which a medical device manufacturer can get approval for his product under the MDA. Consequently, the plurality refused to "infer that Congress intended to have whatever consumer protection might be afforded by common law tort actions preempted in favor of a regulatory scheme that was largely toothless

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[106] *Id.* (Breyer, J., concurring in part and concurring in the judgment).

[107] *Medtronic*, 116 S.Ct. at 2262-63 (O'Connor, J., concurring in part and dissenting in part).

[108] *Id.* at 2263 (O'Connor, J., concurring in part and dissenting in part).

[109] *Id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

[110] 682 A.2d 724 (N.J. Super. Ct. App. Div. 1996).

[111] *Id.* at 732.

because of the MDA's 'grandfathering' and 'substantially equivalent' provisions."[112] Unlike the MDA, however, under FIFRA, pesticides and pesticide labels are subject to a thorough review by the EPA, and specific labeling content is mandated under regulations.[113] Furthermore, almost all pesticides and pesticide labels are subject to the EPA's rigorous review; there are no provisions for abbreviated review as there are in the MDA.[114] In addition, plaintiffs are not denied relief entirely by the preemption provisions of FIFRA; products liability claims such as a claim of defective design escape FIFRA's preemption as long as they are not grounded in a claim of inadequate labeling.[115] Therefore, FIFRA is fundamentally different from the MDA, and courts should recognize this.

Second, the language of FIFRA's preemption statute is different in significant ways. Both *Cippolone* and *Medtronic* state that the ultimate question is whether Congress intended preemption.[116] Whereas the MDA's language is somewhat vague in that it never refers with any specificity to the state requirements it seeks to preempt,[117] FIFRA is clear in its aim: it seeks to preempt "any requirements for labeling or packaging"[118] that interfere with federal law. Congress has thus spoken clearly in FIFRA with regard to its intent to preempt failure to warn claims.[119] It also bears mentioning again that the preemption provisions under FIFRA bear the heading "Uniformity," which further indicates Congress' preemptive intent. In this regard, the FIFRA preemption statute bears more resemblance to the statute at issue in *Cippolone* than the MDA provision at issue in *Medtronic*.

Third, the argument that the word "requirements" does not include state common law tort actions is an argument applicable to the FIFRA statute. This argument, however, was supported by only a plurality of the *Medtronic* Court. In fact, a majority of the Justices concluded that the term "requirements" did indeed encompass state common law tort actions.[120] Furthermore, as previously mentioned, the intent of Congress

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[112] *Id.* at 731.

[113] *Id.*

[114] *Id.*

[115] *Id.*

[116] *Lewis*, 682 A.2d at 729-30 (citing Cippolone v. Liggett Group, Inc., 505 U.S. 502, 516 (1992), and Medtronic v. Lohr, 116 S. Ct. 2240, 2250 (1996)).

[117] *See* the text of the MDA preemption statute, *supra* note 85.

[118] 7 U.S.C. § 136v.

[119] *Lewis*, 682 A.2d at 730, 732.

[120] *Id.* at 731.

in this instance dictates that the term must be construed to include state common law tort actions, or the true intent of Congress would not be reflected in the statute. The better result would be reached if the Court returned to *Cippolone* and held that the term "requirements" can (and as used in FIFRA does) encompass state common law tort actions.

CONCLUSION

Although doubt may have existed at one time about the preemptive effect of section 136v, and although the Supreme Court has given unclear signals from its decisions in *Medtronic* and *Cippolone* as to whether it would decide FIFRA preempts state common law failure to warn claims, the lower courts are in general agreement that Congress intended under FIFRA to preempt such claims. Perhaps the most significant reason that courts have concluded FIFRA does not preempt state common law failure to warn claims is that plaintiffs may not have a theory of recovery if preemption is found. The sympathy of a court should not blind it to the clear intent of Congress in the statutory language itself. It is by necessity, for the sake of uniformity, that such actions are preempted. Disapproval of the decision of Congress to make uniformity important to the Act should be directed to Congress, and should not be grounds for judicial activism and creative problem-solving by the courts. Perhaps, in the end, the only way to resolve the inconsistencies among the courts is for Congress or the Supreme Court to speak with unmistakable clarity on the issue, so that those dissonant courts will no longer have an avenue to grasp for what appears to be an equitable result.