

BATES ENVIRONMENTAL AMICUS BRIEF

INTRODUCTION AND INTEREST OF AMICI

This brief addresses the issue of whether the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), 7 U.S.C. §§ 136 et seq., preempts state damage claims arising out of the use of federally registered pesticides. Amici have actively participated in pesticide regulatory proceedings under FIFRA. That experience has demonstrated that FIFRA and state damage actions complement and, in fact, reinforce one another in a constructive way that strengthens protection of public health, workers, and the environment. [LESLIE WILL FIX]

SUMMARY OF ARGUMENT

FIFRA charges registrants with ensuring that their pesticide products will not have unreasonable adverse health and environmental effects and with writing pesticide labels that achieve this result. Once the Environmental Protection Agency (“EPA”) approves a pesticide use under this standard, the pesticide may then be sold and used in the United States.

EPA’s past approval of a pesticide label, however, affords no guarantee that the pesticide use will comply with FIFRA’s “unreasonable adverse effects” standard over time as regulatory standards change and new evidence emerges. FIFRA commands the registrant to keep EPA apprised of any information documenting adverse effects from a pesticide use and to seek changes in the registration and EPA-approved label when warranted by such new information or changing conditions. A pesticide is misbranded and subject to FIFRA enforcement measures if its label, even if federally approved, does not provide adequate health and environmental protection. For example, if EPA initially registered a pesticide that harms workers in the 1950s and has yet to complete re-registration of that pesticide under current standards, the registrant may well be liable for misbranding and EPA’s registration of the pesticide and approval of the

label would offer no defense. This potential misbranding liability evinces Congress's intent that FIFRA would be a fluid scheme, obligating registrants to provide EPA adverse effects information and to update their labels to reflect such information and current standards.

Common law tort liability similarly imposes obligations to ensure that product design and labeling will avoid unreasonable adverse health and environmental effects. State damage actions can identify shortcomings in previously approved FIFRA registrations and labels and prompt registrants to remain vigilant in ensuring that their labels provide adequate health and environmental protection. State damages actions that create parallel incentives to avoid unreasonable harm serve as a catalyst for registrants to modify their pesticide products and labels when warranted by evolving legal standards, emerging science, and evidence of harm from existing uses.

ARGUMENT

I. FIFRA ESTABLISHES A FLUID REGULATORY SCHEME IN WHICH PESTICIDE REGISTRATIONS AND EPA-APPROVED LABELS MUST CHANGE TO CONFORM TO UPGRADED HEALTH AND ENVIRONMENTAL STANDARDS AND NEW EVIDENCE OF HARM.

A. FIFRA Imposes a Duty on Pesticide Registrants to Ensure that EPA's Registration of a Pesticide At All Times Avoids Unreasonable Adverse Health and Environmental Effects.

Congress originally enacted FIFRA in 1947 to protect farmers from adulterated and ineffectual pesticide products. For over three decades, FIFRA had no health or environmental protections. In 1972 in the wake of Rachel Carson's A Silent Spring and the controversy over DDT, Congress adopted a sweeping overhaul of FIFRA that made health and environmental protections its centerpiece. See Pub. L. No. 92-516, 86 Stat. 996 (1972); H.R. Rep. No. 511, 92d Cong., 1st Sess. (1971). The amended FIFRA established a scheme in which EPA must assess and determine allowable pesticide use based on the increasing body of scientific evidence

indicating that pesticides pose risks to human health and the environment.

As amended, FIFRA establishes a federal-state partnership with minimum federal standards that can generally be supplemented but not reduced by the states. Under this scheme, a pesticide may generally not be sold or used in the United States unless it has an EPA registration for the specific use of that particular pesticide. 7 U.S.C. § 136a(a). EPA registers a pesticide upon determining that the labeling complies with FIFRA's requirements, that composition claims are warranted, that the pesticide will perform its intended function, and that the pesticide use will not cause unreasonable adverse effects on health or the environment. 7 U.S.C. § 136a(c)(5). This last criterion embodies FIFRA's health and environmental protection standard.

EPA must classify pesticides as general or restricted use pesticides, depending on the risks posed to human health and the environment. Where necessary to prevent unreasonable adverse health or environmental effects, EPA must classify a pesticide as restricted use. 7 U.S.C. § 136a(d)(1)(C). Restricted use pesticides are subject to additional regulatory restrictions, particularly concerning application of the pesticide. Id.

FIFRA requires a person seeking to register a pesticide to demonstrate that the proposed pesticide product meets FIFRA's standards. 7 U.S.C. § 136a(a) and (c); 40 C.F.R. 152.42. The proponent bears the burden of proof and must present sufficient supporting scientific evidence of the pesticide's safety and impact on health and the environment. 40 C.F.R. § 152.50(f)(3). EPA has established protocols and standards for the data required to support a pesticide registration. See generally 40 C.F.R. Part 152. The pesticide company seeking the registration (called the "registrant") generates and submits the scientific studies on which EPA will base its determination. Id.

An EPA registration is essentially a license to market and use a pesticide that conforms to a specified formulation and the use restrictions approved by EPA. The use restrictions are set out on the EPA-approved label affixed to the pesticide product as it moves through interstate commerce. FIFRA makes it unlawful to use a pesticide in a manner inconsistent with the label, *id.* § 136j(2)(G).

The 1972 amendments left existing registrations in place until the registrants submitted newly required data and, based on its assessment of such data, EPA either cancelled or reregistered the pesticide uses with modifications to meet the new health and environmental standard. As of 1986, EPA had reregistered none of the 50,000 pesticides subject to reregistration, and had completed its reassessment of none of the 600 pre-1972 active pesticide ingredients. General Accounting Office, EPA's Formidable Task to Assess and Regulate Their Risks at 3 (1986). Although Congress amended FIFRA in 1988 to accelerate this process and again in 1996 to impose timelines for food related reassessments, EPA still has not completed the reregistration process for numerous old pesticides. *See* 7 U.S.C. § 136a-1.

Because EPA depends so heavily on manufacturer submissions, FIFRA imposes stringent and continuing obligations on registrants to submit complete, up-to-date information to EPA. First, it is unlawful to knowingly falsify any part of an application for registration or other information required to be submitted under FIFRA, as well as to make any false or misleading statement or representation in a pesticide's labeling. 7 U.S.C. §§ 136j(a)(1)(E), 136j(a)(2)(C) & (M); 136(q)(1)(A). Second, registrants have an ongoing obligation to provide EPA with all factual information that they have regarding unreasonable adverse environmental effects. 7 U.S.C. § 136d(a)(2); 40 C.F.R. part 159.

Third, and of critical importance, registrants have a continuing obligation to ensure that

the registration and label complies with FIFRA's requirements. 7 U.S.C. §§ 136j(a)(1)(E), 136(q). Under FIFRA, “the burden is on the registrant to establish that continued registration poses no safety threat.” Envtl. Defense Fund v. EPA, 510 F.2d 1292, 1297, 1302 (D.C. Cir. 1975); 110 Cong. Rec. 2948-49 (1964) (Rep. Sullivan) (“The burden of proof of safety should always be on the manufacturer The burden of proof should not rest on the Government, because great damage can be done during the period the Government is developing the data necessary to remove a product which should not be marketed.”).

To satisfy this burden, registrants must make changes to the registration and labels whenever necessary to protect health and the environment. In turn, FIFRA mandates that “the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this Act.” Id. § 136a(f)(1) (emphasis added).

If EPA determines that the pesticide registration does not comply with FIFRA, EPA may commence administrative proceedings to cancel the pesticide's registration. 7 U.S.C. § 136d(b). EPA may also seize or bar the use or sale of pesticides that violate FIFRA. Id. §§ 136j & 136k; see also id. § 136l (authorizing civil & criminal penalties for FIFRA violations). None of these mechanisms for enforcing FIFRA provides compensation to individuals who suffer injuries as a result of FIFRA violations; nor does any other federal cause of action provide such compensation.

Because cancellation proceedings are time-consuming and cumbersome, EPA rarely brings such actions to compel label changes. Rather, EPA leaves most use and label changes to its ongoing process of reregistering pesticides. However, EPA has yet to reregister thousands of pesticide products were initially registered before the imposition of more stringent data requirements pertaining to human health effects and environmental harm. Because EPA waits

until the culmination of the reregistration process to impose most product and label changes on the registrant, EPA is not currently ensuring that the pesticide registrations and labels for thousands of pesticide products are in compliance with FIFRA. EPA's reregistration backlog makes it all the more critical that pesticide registrants have strong incentives to comply with their obligation to make whatever product and label changes are necessary to comply with FIFRA's requirements. For this reason, the Assistant Administrator of EPA for Pesticides and Toxic Substances took the position in 1994 that:

After reviewing the legal framework and the policy considerations, I conclude that EPA would clearly prefer the legal interpretation that FIFRA does not preempt state tort actions.

Letter from Lynn R. Goldman, Assistant Administrator for Pesticides and Toxic Substances (Jan. 7, 1994) (reproduced in addendum to this brief).

B. FIFRA Imposes an Ongoing Obligation on Registrants To Draft Pesticide Labels That Adequately Protect Health and The Environment.

Unlike federal statutes governing cigarettes and smokeless tobacco, FIFRA does not mandate the precise wording for pesticide labels, *cf.* 15 U.S.C. §§ 1333, 4402(a)(1). Nor do EPA's regulations dictate the specific language to be used for the bulk of each label, as some regulations do. *Cf.* 21 C.F.R. § 801.430(c) (tampon warnings regarding toxic shock syndrome).

Rather, FIFRA leaves the drafting of the label to the registrant. 7 U.S.C. § 136a(c)(1)(C); 40 C.F.R. § 152.50(e). It charges the registrant, not the government, with devising pesticide labels that convey adequate information to prevent "unreasonable adverse effects" to health and the environment. As a result, labels for similar pesticides produced and marketed by different registrants may differ significantly from one another. Such differences are permissible as long as the registrant writes a label that ensures against "unreasonable adverse effects." As EPA has made clear, "[t]he registrant must take responsibility for quality control of the product's

composition and for adequate labeling describing the product, its hazards and uses.” 53 Fed. Reg. 15,956 (May 4, 1988). In contrast to those bound by statutorily prescribed warnings, pesticide registrants have sufficient flexibility to craft labels and make label revisions to ensure that their pesticide labels satisfy both state law obligations and FIFRA’s requirements.

FIFRA and EPA’s labeling regulations establish certain minimum requirements for pesticide labels, such as the inclusion of certain terms to reflect the acute poison risk posed by a particular pesticide. Inclusion of such FIFRA mandated statements, however, does not satisfy the registrant’s FIFRA obligations. The label must also contain directions for use that guard against unreasonable adverse effects. Moreover, FIFRA allows labels to contain information that goes beyond those requirements, and EPA never assesses whether a label complies with other legal obligations.

A registrant has a duty to submit revised labels for EPA approval whenever the existing label falls short of meeting FIFRA’s requirements. Many label revisions require only EPA notification, not agency approval, 40 C.F.R. § 152.46(a), and some revisions, such as changes in nonmandatory label statements, additions required by other federal laws, or changes in the label format, do not even require EPA notification. 40 C.F.R. § 152.46; see also id. §§ 152.130(b) & (c); 152.132(d)(5). As such, it is the registrant who decides that a label change is necessary and who drafts a revised label. EPA must allow the label change to be made unless it would violate FIFRA.

A pesticide is misbranded if, notwithstanding EPA’s registration of the pesticide and acceptance of the label, it fails to contain whatever additional warnings are necessary to protect against unreasonable adverse health and environmental effects. 7 U.S.C. § 136(q)(1)(F)-(G). The fact that EPA has approved a label is no defense to a claim under FIFRA that the product is

misbranded. Id. §§ 136(q)(1)(A), 136a(f)(2). In other words, the fact that a pesticide label has been approved does not immunize the registrant from liability for violating its FIFRA obligations. Indeed, EPA has recognized that “[f]or liability reasons, companies often voluntarily provide additional information on the label, particularly in the area of precautionary statements.” 49 Fed. Reg. at 37,960, 37,971 (Sept. 26, 1984). Nothing in FIFRA or EPA’s regulations prohibits including such label warnings, provided that they do not violate any specific requirement imposed by FIFRA or its implementing regulations. Id.

C. FIFRA’s Preemption Provision

FIFRA contains a section, entitled “Authority of States,” which affirms state authority to supplement federal pesticide regulation:

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

7 U.S.C. § 136v(a) (emphasis added). Through this provision, Congress expressly made it plain that FIFRA left room for state supplementation that affords more, but not less, health and environmental protection.

Immediately following this subsection is FIFRA’s label preemption provision, which provides:

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.

7 U.S.C. § 136v(b). This provision does not pertain to state damages actions at all, since “[s]uch State” refers back to the preceding provision, which refers to states that “regulate” pesticide sale or use through “regulation.” The reference to state requirements is therefore limited to regulations, which are generally understood to embody statutes or legislative-type rules. See Cipollone v. Liggett, 505 U.S. 504, 519, 523 (1992) (“regulation” most naturally refers to

positive enactments of regulatory bodies, not to common law damages remedies). Even if it is construed to apply to state damages actions, the preemption provision is limited to those labeling or packaging requirements that are “in addition to or different from” those required under FIFRA. The linchpin would, therefore, be whether state law obligations create duties in addition to or different from FIFRA’s unreasonable adverse effects standard. As explained below, state law obligations do no such thing.

A third subsection authorizes a state to register additional uses of federally registered pesticides for distribution and use in that state to meet special local needs. 7 U.S.C. § 136v(c). Neither the state nor EPA must find that the pesticide use will avoid unreasonable adverse effects before issuance of a special local need permit. However, a state may not issue such a permit if EPA has previously denied, disapproved, or cancelled registration for that use. *Id.*

None of FIFRA’s state authority provisions directly addresses the viability of state damage actions. The only explicit legislative discussion of FIFRA’s preemptive effect on state damage actions came in 1982 during congressional debates over an amendment that would have provided federal injunctive relief for persons injured by pesticides. In the course of these debates, several House Members and EPA indicated their belief that state tort remedies were generally available. 128 Cong. Rec. 20,498, 20,504 (1982) (Representative Wampler stated he knew of no case “where a private citizen had not been able to sue in state courts for redress of grievances.”); *Id.* at 20,502 (Representative Panetta explained that the amendment would provide federal injunctive relief but leave individuals harmed by pesticides state court remedies for money damages); *id.* at 20,500 (Representative Thomas explained that, without the amendment, individuals would merely have “State rights in terms of suing for damages, negligence, nuisance”); Testimony of John A. Todhunter, Reauthorization of the Federal Insecticide,

Fungicide, and Rodenticide Act: Hearings on S. 2245, S. 2620 and S. 2621 Before the Senate Committee on Agriculture, Nutrition and Forestry, 97th Cong., 2d Sess. (1982) (testimony of EPA official explaining that EPA believed the amendment was unnecessary because “it is something we feel people have under existing laws other than FIFRA and our preference would be not to see FIFRA cluttered up with additional amendments putting those particular things in FIFRA”).¹ Therefore, the only evidence directly on point reveals that Congress believed that individuals harmed by pesticides continue to have recourse to state damage actions under the FIFRA scheme.

II. STATE LAW LIABILITY REINFORCES FIFRA’S REQUIREMENTS, IMPOSING OBLIGATIONS THAT PRECIPITATE SPEEDIER FIFRA COMPLIANCE AND COMPLEMENTARY SAFEGUARDS TO PROMOTE FIFRA’S GOAL OF PROTECTING HEALTH AND THE ENVIRONMENT.

In Wisconsin Public Intervenor v. Mortier, 501 U.S. 597 (1991), the Supreme Court held that FIFRA does not preempt local regulation of pesticide use. While the Court stated that “the 1972 amendments turned FIFRA into a ‘comprehensive regulatory statute,’” *id.* at 613 (quoting Ruckelshaus v. Monsanto, 467 U.S. 986, 991 (1984)), it recognized that “FIFRA nonetheless leaves substantial portions of the field vacant . . . FIFRA nowhere seeks to establish an affirmative permit scheme for the actual use of pesticides. It certainly does not equate registration and labeling requirements with a general approval to apply pesticides throughout the Nation without regard to regional and local factors like climate, population, geography, and water supply.” Wisconsin Public Intervenor, 501 U.S. at 613-14. Moreover, the Court concluded that FIFRA’s specific grant of authority to states to regulate pesticide sale and use “acts to ensure that the States could continue to regulate use and sales even where, such as with

¹ The House passed the amendment offered by Representative Panetta, but the substitute measure that passed the Senate Forestry and Agriculture Committee did not contain that

regard to the banning or mislabeled products, a narrow pre-emptive overlap might occur.” *Id.* at 614.

Just as local pesticide regulation may complement and fill gaps in federal regulation under FIFRA, state damages actions likewise further the state’s preserved authority to regulate pesticide sale and use. The common law duty to warn users and the public of pesticide hazards reinforces the registrants’ duty to ensure that their labels guard against unreasonable adverse effects. Moreover, some state legal obligations also buttresses the registrants’ duties to provide EPA up-to-date information about pesticide hazards so that EPA can ensure that previously issued registrations continue to protect the public.

A. FIFRA’s Express Recognition of State Authority to Regulate Pesticide Sale and Use Supports the Availability of State Damages Actions That Would Lead to Sale and Use Restrictions.

Under FIFRA, a state may ban the sale or use of a federally registered pesticide or may impose restrictions on its use beyond what EPA has imposed. For example, the States of Massachusetts and Wisconsin imposed restrictions on the use of daminozide on apples after EPA determined that it was a carcinogen, but before EPA took action to restrict its use. *See* Mass. Ann. Laws ch. 94, § 192 (1991); Wis. Stat. § 94.707(1m) (1989). Similarly, states have banned or restricted the use of other pesticides that EPA had permitted to be used. *See, e.g.,* CAL. HEALTH & SAFETY CODE § 111246 (2002) (lindane); IOWA CODE ANN. § 206.32 (1989) (chlordan); MD. CODE ANN. AGRIC. § 5-210.5 (1989) (chlordan, heptachlor, aldrin and dieldrin); MINN STAT. § 18B.115 (1990) (chlordan and heptachlor); WIS. STAT. § 94.707(a)-(b)(1987-1988) (2-4-5 trichlorophenoxyacetic acid and silvex).

State authority to ban or impose constraints on pesticide use in a regulatory capacity is

amendment. S. Rep. No. 511, 97th Cong., 2d Sess. (1982).

similar in its ultimate result to many types of state damages actions. While a regulatory ban directly prevents harm before the fact, state damages actions allow individuals harmed by pesticide use to sue for damages to compensate for their losses. The underlying legal duty in such a case may require the pesticide manufacturer to avoid designing, marketing, or selling a pesticide for a use that causes the same type of harm an affirmative state regulation may seek to prevent. If a state can affirmatively ban a pesticide to prevent harm to its citizens, as it can under the FIFRA scheme, it also can allow its citizens to enforce and seek redress for violations of legal duties in lawsuits that may indirectly produce the same result.

An apt example is provided by litigation over the pesticide phosdrin, a highly toxic nerve-agent, which caused acute poisonings of farmworkers. In the summer of 1993, Amvac Corp. marketed phosdrin for the first time in Washington state, even though more than 600 suspected poisonings of workers, including three deaths, were reported in California from 1982 through 1989. Amvac had acknowledged that the existing FIFRA registration and label did not adequately protect workers, EPA had directed Amvac to develop and implement mandatory restrictions on phosdrin use to protect workers, and California had already imposed some such restrictions. Upon finding the FIFRA requirements inadequate, the Washington Department of Agriculture adopted an emergency regulation requiring worker training, wind restrictions to lessen drift, and safeguards to protect workers who mix and apply the pesticide. Tragically, however, throughout the summer of 1993, 29 workers reported acute pesticide poisoning from exposure to phosdrin. The Washington Department of Agriculture banned all phosdrin use before the end of the summer to stop the stream of worker poisoning incidents. The following year, EPA, which had been conducting a review of phosdrin's worker impacts, concluded that phosdrin caused unreasonable adverse effects to workers. In the summer of 1994, shortly after

EPA announced its intent to take steps to suspend phosdrin's registration, Amvac requested a voluntary cancellation of its FIFRA registration for phosdrin. 59 Fed. Reg. 38,973 (August 1, 1994); 60 Fed. Reg. 17,357 (April 5, 1995).

The workers became casualties of EPA's delays in canceling registrations of pesticides that do not meet FIFRA's unreasonable adverse effects standard. Three of the workers sued both Amvac and the distributor for marketing and distributing a defectively designed product. The Washington Supreme Court upheld their right to bring such a claim under state law, Ruiz-Guzman v. Amvac Chemical Corp., 7 P.3d 795 (Wash. 2000), and the Ninth Circuit held that FIFRA did not preempt the workers' design defect claims. Ruiz-Guzman v. Amvac Chemical Corp., 243 F.3d 549 (9th Cir. 2000). Ultimately, the case resulted in a settlement. The injured workers' ability to seek damages promoted FIFRA's purpose of protecting workers against unreasonable adverse effects from pesticides.

A similar situation occurred in connection with a rat poison that tasted sweet and looked like candy. Although the label cautioned to keep the rat poison out of reach of children and that the poison might be harmful if swallowed, a nine-year-old boy ate some of the poison when he found it at a boys' club and ultimately died as a result. A jury awarded his family compensatory and punitive damages upon finding that the registrant withheld incidents of human exposure from EPA and that the product could have been designed with a bittering agent to avoid being mistaken for candy and with a substance that would induce vomiting. The Georgia Supreme Court held that FIFRA preempted the failure-to-warn claim and that a new standard governed the design defect claim Banks v. ICI Americas, Inc., 264 Ga. 732, 734, 450 S.E.2d 671, 673 (1994).

State damages actions play a particularly important role in promoting FIFRA's health and safety goals given the backlog in EPA re-registrations. Ever since Congress made health and

environmental protection the linchpin of FIFRA in 1972, EPA has been struggling to review and re-register pesticides under the unreasonable adverse effects standard. State damages actions bring to light the harms certain pesticides are causing during this drawn-out process.

EPA is continually upgrading registration requirements to address emerging evidence of adverse effects. For example, for years, workers have been exposed to harmful and sometimes lethal doses of pesticides when they re-enter sprayed areas. While pesticide registrations establish prohibitions on worker re-entry during specified re-entry periods, the specified periods have often proved to be insufficient to protect the workers from acute poisonings. As part of its implementation of a worker protection standard promulgated in 1992, [40 C.F.R. § 170.112](#), and its re-registration process, EPA is reviewing and expanding the re-entry periods. However, workers have been subjected to excessive exposures to acutely toxic pesticides in the meantime.

Not only is the re-registration process plagued by delay, but EPA is sometimes unwilling to take action that would constrain certain pesticide uses, particularly where the scientific basis for the constraint is questioned by the registrant. For example, in 1984, after finding that arsenic-treated wood products posed excessive cancer and birth defect risks, EPA announced its intent to cancel registrations of arsenic products used to treat wood unless consumer warnings and precautionary information are provided to wholesalers, distributors, and retailers to be passed along to consumers. 49 Fed. Reg. 28,666 (July 13, 1984). Two years later, EPA accepted a voluntary, instead of mandatory, consumer awareness program undertaken by industry. 52 Fed. Reg. 1334 (Jan. 10, 1986). After acceptance of this voluntary program, reports of people being poisoned and playground structures and decks being contaminated by arsenic-treated wood continued to surface, precipitating dozens of lawsuits against the makers and distributors of arsenic-treated wood. Adam Liptak, [The Poison is Arsenic, and the Suspect Wood](#), THE NEW

YORK TIMES, at A1, June 19, 2002 ; Environmental Working Group and Healthy Building Network, Poisoned Playgrounds, 13-14 (2001). In response, the industry and EPA agreed to a phase-out of arsenic-treated wood for residential uses. 67 Fed. Reg. 8244 (Feb. 22, 2002); http://www.epa.gov/pesticides/factsheets/chemicals/cca_transition.htm.

State damages actions, like those seeking redress for poisonings and contamination from arsenic-treated wood, promote FIFRA's goal of preventing adverse health and environmental effects from pesticide use. Since FIFRA expressly authorizes states to regulate pesticide sale and use directly, it must also be read to preserve state damages actions that indirectly further this goal.

B. Failure-to-Warn Actions Reinforce the Registrant's Duties to Ensure that Pesticide Labels Meet FIFRA's Standards.

If FIFRA preemption extends to state damages actions at all, it preempts only those failure-to-warn claims that require a label that is "in addition to or different than" that required under FIFRA. 7 U.S.C. § 136v(b). Since FIFRA requires labels to ensure that the pesticide use will not cause unreasonable adverse health or environmental effects, state failure-to-warn duties reinforce FIFRA's label requirements.

Few, if any, state tort claims allege that manufacturers should have required different label warnings from those required under FIFRA because most state duty-to-warn obligations are subsumed within FIFRA's unreasonable adverse effects standard and its misbranding mandate, i.e., they challenge a failure to provide sufficient warnings to prevent unreasonable adverse effects. Where plaintiffs are seeking redress for a failure to relay critical warnings to the public, state damage actions do not impose any labeling requirements that are "in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). Instead, they provide a means for individuals who are harmed by misbranded pesticides to obtain compensation for that harm. The

remedial measures that the registrant would take to avoid such liability would either consist of label changes that would be required under FIFRA in any event, or other means of conveying information -- such as pamphlets, advertisements, and notices in publications -- which are not subject to FIFRA's labeling requirements.

In Jenkins v. James B. Day & Co., 634 N.E.2d 998 (Ohio 1994), the Ohio Supreme Court reached this conclusion with respect to the Federal Hazardous Substances Act (“FHSA”), which preempts state cautionary labeling requirements that are not identical to applicable federal labeling requirements. 15 U.S.C. § 1277(b)(1)(A). The court held that FHSA labeling requirements do not preempt state duty-to-warn claims because they are identical; both require the manufacturer to design product labels that “protect against the [] risk of illness or injury.” Id.

As under the FHSA, the possibility of state tort liability creates additional incentives for manufacturers to ensure that their labels contain the most complete and accurate information available to protect health and the environment. It is particularly important to maintain strong incentives for registrants to make necessary labeling changes, given that it will be many years before EPA completes its assessment of existing labels as part of the pesticide reregistration process. A contrary reading would permit a manufacturer, who knew of dangers from use of the pesticide as directed on the label, to refrain from informing EPA of needed label changes and then to hide behind the very label it knew to be inadequate. Such a result was never contemplated by Congress and should not be countenanced by the courts.

It makes eminent sense for Congress to preempt state regulatory labeling requirements, while allowing state damage actions that challenge the adequacy of pesticide labels. In order to guard against duplicative label approval schemes burdening interstate commerce, Congress sought to ensure that manufacturers would have one label nationwide, rather than different ones

in each state. A reading of 7 U.S.C. § 136v(b) to encompass state regulations, but not damage actions, accomplishes that result. No state can establish a label approval scheme. Since the registrant must use an EPA-approved label, pesticide labels for particular products will be uniform throughout the United States.

State damage actions, however, serve to highlight defects in the EPA-approved labels. It is hard to imagine state damage actions leading to conflicting labels because the manufacturer retains the ability to draft the label to meet all its obligations. Instead, state damage actions create an incentive for registrants to submit more complete and informative labels to EPA for approval and to ensure that pesticides are not misbranded by virtue of inadequate warnings of health and environmental effects. Compliance with any such state common law obligation to provide warnings and precautionary information on the pesticide label promotes the overall FIFRA goal of protecting the public from the adverse effects of pesticide use, without creating any conflict between a manufacturer's FIFRA obligations and compliance with that duty.

For example, Rumsey v. Freeway Manor Minimax, 423 S.W.2d 387 (Tex. Civ. Appeals Ct. 1968), involved a three-year-old boy's ingestion of a roach poison, which led to his death. The court of appeals held that the evidence could support a finding of negligence because the label identified an antidote when, in fact, there was no antidote for the insecticide. Such a finding would likely spur the registrant to modify the label to disclose the lack of an antidote and the full risks of ingestion of the poison.

Likewise, in 1999, crawfish farmers brought a class action lawsuit alleging fraudulent and negligent misrepresentation for introducing and marketing the insecticide fipronil for use on rice crops in Louisiana. Fipronil is highly toxic to aquatic invertebrates, including crawfish, and in Louisiana, rice and crawfish farms occur in close proximity, often in the same pond. The

farmers used fipronil on rice seed to combat the rice water weevil, but suffered significant declines in crawfish production in adjacent areas. The class action resulted in a \$45 million settlement in March 2004. A few months later, the registrant asked EPA to cancel registration of its pesticide products containing fipronil for use on rice. 69 Fed. Reg. 39,927 (July 1, 2004).

Similarly, in 1997, EPA made a finding that the fungicide benomyl caused unreasonable adverse effects based on, inter alia, evidence of birth defects, including rats borne without eyes or with very small eyes after in utero exposure to benomyl. 42 Fed. Reg. 61,788 (1977).

Initially, EPA proposed to cancel benomyl registrations unless the labeling warned that “benomyl causes birth defects and reduced sperm production in laboratory animals. Exposures to benomyl during pregnancy should be avoided.” 44 Fed. Reg. 51,166, 51,169 (1979). In its final determination, EPA backtracked and required that the label state only: “Harmful if inhaled. Wear a cloth or disposable paper dust mask during handling and mixing.” 47 Fed. Reg. 46,747, 46,750 (1982). Over the years since, dozens of children in rural areas have been borne with no or tiny eyes after their mothers were exposed to benomyl during pregnancy. A jury awarded \$4 million to the family of one such child whose mother was exposed by applications at a nearby farm. Castillo v. E.I. DuPont de Nemours, Co., 854 So.2d 1264 (Fla. 2003).

While EPA initially addressed the potential for birth defects from benomyl through label warnings, it is certainly possible that the company may decide to stop marketing the pesticide for uses that could expose pregnant women or that EPA or a state may decide to prohibit such uses. Under FIFRA, a state would have the authority to ban use of a pesticide that could not be used, even with extensive warnings, without causing unreasonable adverse effects, such as birth defects. As the Supreme Court observed in Wisconsin Public Intervenor, FIFRA’s express grant of authority to regulate pesticide use “acts to ensure that the States could continue to regulate use

and sales even where, such as with regard to the banning or mislabeled products, a narrow preemptive overlap might occur.” *Id.* at 614.

C. State Damages Actions Fill Gaps in the FIFRA Regulatory Scheme.

Many courts holding that FIFRA preempts state damages actions have assumed that EPA has made a finding that predetermines the outcome of the state law question that would be presented to a jury in such a case. While FIFRA’s unreasonable adverse effects standard resembles the legal duty underlying some state law duties, EPA does not even purport to guard against unreasonable adverse effects in certain contexts.

1. *State Law Liability For Fraud Promotes the FIFRA Scheme.*

Holding pesticide registrants liable for fraud promotes the FIFRA scheme because EPA is dependent upon accurate, timely, and complete information from registrants about the impacts of registered pesticides. As explained above, FIFRA is predicated on the registrants’ duties to submit accurate data to support a registration, to keep EPA informed about new adverse effects information, and to seek changes to registrations and labels, as required by such new information. It would defy the FIFRA scheme for protecting public health and the environment if FIFRA shields a registrant from liability for concealing the facts that EPA needs to determine what protections must be required.

For example, beginning in 1989, growers reported crop damage from Benlate 50 DF, a fungicide pesticide product. Faced with thousands of crop damage reports in 40 states, DuPont recalled Benlate 50 DF and began paying growers compensation. DuPont discontinued making payments in 1992, however, claiming that its research showed Benlate was not responsible for the crop damage. Growers then sued for compensation. After several cases had been resolved through settlement or trial, a Hawaii court ordered DuPont to release preliminary test data that showed Benlate had been contaminated by a powerful weedkiller also produced by DuPont. The

disclosure led to judge-imposed fines against DuPont for withholding evidence and a shareholder action for making false and misleading statements about Benlate. Benlate Timeline, THE NEWS JOURNAL, April, 20 2001, available at www.delawareonline.com/newsjournal/busienss/2001/04/20benlatetimeline.html; Benlate's Lab Tests at Odds, THE TAMPA TRIBUNE, May 4, 1995, at 1. After reviewing the concealed documents, Florida's Agricultural Commissioner notified DuPont: "[M]y scientific staff have reached the conclusion that the DuPont corporation has known for years about certain phytotoxic effects of Benlate. It is clear to me that if these files had been provided to my department or the Environmental Protection Agency during the registration process, the data on Benlate DF would have been soundly rejected for use in the registration process." John McGhie, Benlate: The File Grows Round the World, THE OBSERVER, June 6, 1993. Ultimately, in 2001, DuPont voluntarily cancelled its Benlate registration. 67 Fed. Reg. 1979 (Jan. 15, 2002).

EPA cannot make credible unreasonable adverse effects determinations if the registrant withholds adverse effects data. State law claims based on a company's fraudulent withholding of such data from EPA holds the company accountable for its wrongdoing and makes the concealed information available for EPA review and action.

2. *EPA Does Not Review or Make Findings Concerning Pesticide Efficacy for Most Pesticides.*

A 1978 FIFRA amendment expressly authorized EPA to waive data requirements pertaining to a product's efficacy and to register such pesticides without determining that the composition warrants proposed claims of efficacy. 7 U.S.C. § 136a(c)(5). The amendment also established a presumption that any state efficacy findings would make EPA efficacy review unnecessary. Id. Pursuant to this authority, EPA waived review of efficacy claims for most pesticides. 40 C.F.R. § 158.640(b). Accordingly, EPA registers most pesticides without

determining whether their composition warrants the efficacy claims made by the registrant.

3. *FIFRA Allows Temporary Authorizations of Pesticide Uses that Lack FIFRA Registrations.*

Under FIFRA, some pesticide uses may be authorized even though the particular pesticide use has not passed muster under FIFRA's "unreasonable adverse effects" standard. First, states may register federally registered pesticides for additional uses that are not permitted on the pesticide label. 7 U.S.C. § 136v(c). Such state registrations, known as special local need registrations, become effective upon state approval and remain effective until rescinded by the state or by EPA. As part of the state approval, the state prescribes directions for use, including the information that must be provided to users or the public. No EPA approval is required for a state local needs permit to become effective.

Second, FIFRA authorizes EPA to exempt state or federal agencies from FIFRA requirements in emergency conditions. 7 U.S.C. § 136p. Under this authority, EPA grants temporary exemptions from EPA registration requirements for particular uses of pesticides that are not permitted under FIFRA registrations. Typically, a state requests an emergency exemption and submits to EPA proposed conditions for the pesticide. Upon obtaining EPA approval, the state then authorizes and imposes the agreed-upon conditions on the pesticide use. While EPA makes an unreasonable adverse effects determination for an emergency exemption, it does so based on an expedited review of far more limited information than required for a registration and focusing on the impacts of the use for only one year, even though emergency exemptions may be sought for successive years. 40 C.F.R. § 166.26(b).

For example, in Macias v. State of California, 897 P.2d 530 (Cal. 1995), a boy who became blind after being sprayed by malathion as part of California's medfly eradication program brought a failure-to-warn claim. The California Department of Food and Agriculture

had issued a special local need registration and obtained an emergency exemption to allow use of malathion for an unregistered use. The case challenged the manufacturer's and the state's failure to warn the public of the health hazards posed by the aerial spraying. While the California Supreme Court did not allow the boy to challenge the manufacturer's failure to provide warnings in connection with a state-administered emergency program, it did not find the claim against the state to be barred. Nothing in FIFRA precluded the state from requiring public notification of the health risks of the aerial spraying, particularly since the state established the parameters of the spraying program embodied in its special local needs permit and medfly eradication program.

4. *EPA Routinely Allows Use of Existing Stocks of Cancelled Pesticides Without Ensuring that the Use of those Stocks Will Avoid Unreasonable Adverse Effects.*

Even when EPA determines that a pesticide use causes unreasonable adverse effects and the registration must be cancelled, it routinely allows existing stocks to continue to be sold and used for a period of months and often years. While EPA must determine that the sale or use of existing stocks "is not inconsistent with the purposes of" FIFRA, 7 U.S.C. § 136d(a)(1), it often allows continued use of existing stocks in return for a registrant's voluntary cancellation of a pesticide, which eliminates the need for often lengthy cancellation proceedings. The courts have upheld EPA's broad assessment of the risks posed by the pesticide, taking into account reduced use due to a settlement agreement, rather than only the risks posed by use of the existing stocks. National Coalition Against the Misuse of Pesticides v. EPA, 867 F.2d 636 (D.C. Cir. 1989); Northwest Food Processors Ass'n v. Reilly, 886 F.2d 1075, 1080 (9th Cir. 1989). Where a pesticide use is being cancelled to avoid unreasonable adverse health or environmental effects, particularly those associated with acute pesticide poisoning, but existing stocks may continue to be used, the individuals who suffer as result are left unprotected under FIFRA.

5. *Some Common Law Obligations Require Off-Label Warnings.*

While some failure to warn claims might spur the registrant to strengthen the warnings on the EPA-approved label, others seek warnings that cannot be provided through the product label. FIFRA labels are attached to the pesticide product as it moves through the streams of commerce. While they may convey warnings and directions for use to the direct purchaser or user, labels do not reach members of the public who may be unwittingly exposed to pesticides.

For example, spray drift is a key mechanism through which pesticides migrate away from their target and cause harm to the public. States receive about 2500 complaints of drift each year, and many more go unreported. http://www.epa.gov/opppmsd1/PR_Notices/prdraft-spraydrift801.htm, at 3. Many pesticide labels include a general direction, such as “Do not allow drift,” but EPA has recently proposed to require clearer and more specific directions for preventing spray drift, which establish no-spray buffer zones, maximum wind speeds, and aerially equipment limitations. 66 Fed. Reg. 44,141 (Aug. 22, 2001); http://www.epa.gov/opppmsd1/PR_Notices/prdraft-spraydrift801.htm.

Ordinarily, the pesticide purchaser or applicator will see the pesticide label. Pesticide drift, however, can reach neighboring homes and farms, schools in the vicinity, and the public at large. There is a growing body of evidence, for example, that the children of farmworkers are exposed to pesticide residues in their homes both as a result of drift and residues on their parents’ clothing. *See, e.g.,* Thompson, Beti, *et al.*, “Pesticide Take-Home Pathway Among Children of Agricultural Workers,” 45 J. Occ. Env’tl Med. 42 (2003) (take home exposure and drift present increased risk for farmworker children); Fenske, Richard, *et al.*, “Strategies for Assessing Children’s Organophosphorous Pesticide Exposures in Agricultural Communities,” 10 J. Expos. Anal. Env’tl Epid. 662 (2000) (levels of pesticides in farmworker children from drift and take home exposures exceed EPA safe levels in substantial fraction of farmworker children). There

have also been numerous instances of school children being sprayed inadvertently by pesticides. Cite. Many lawsuits have been brought by such innocent bystanders who did not choose to use the pesticide but were nonetheless exposed and harmed. See, e.g., Castillo v. E.I. DuPont de Nemours, 854 So.2d 1264 (Fla. 2003). In none of these instances would a pesticide label warning have reached the injured party to allow them to avoid being in harm's way.

FIFRA's preemption provision is limited to "labeling or packaging," which FIFRA defines as the material intended to accompany the pesticide through the streams of commerce. Pesticide labeling does not encompass all communications made by a manufacturer in connection with the sale or marketing of a pesticide product. FIFRA, therefore, leaves the registrants other means to convey information to pesticide purchasers and users, none of which needs to be submitted to EPA as part of the approval process. See, e.g., 40 C.F.R. § 152.168(b).

Two federal courts of appeals have distinguished between pesticide labels, which go to the purchaser of the pesticide, and other communications designed to warn the general public of risks of pesticide uses. In Chemical Mfrs. Specialties Ass'n v. Allenby, 958 F.2d 941, 946 (9th Cir.), cert. denied, 113 S. Ct. 80 (1992), the Ninth Circuit held that FIFRA does not preempt point-of-sale warnings on products containing carcinogens and reproductive toxins mandated by California's Proposition 65 because:

FIFRA's definition of labeling cannot encompass every type of written material accompanying the pesticide at any time. If this were true, then price stickers affixed to shelves, sheets indicating that a product is on sale, and even the logo on the exterminator's hat would all constitute impermissible labeling.

Although there was no question that Proposition 65, as an affirmative enactment, is a state regulation within the meaning of FIFRA's preemption provision, the court held that Proposition 65 warnings do not constitute labeling requirements under FIFRA. Id. at 946-47.

Similarly, in New York State Pesticide Coalition v. Jorling, 874 F.2d 115 (2d Cir. 1989),

the Second Circuit refused to construe the term “labeling” in § 136v(b) to include warnings given to customers who contract for pesticide services or public notification of pesticide applications. Because a construction of “labeling” to include anything that could be said to “accompany” a pesticide would literally include “the logo on the applicator's hat and the license plate on the vehicle in which the pesticide is transported,” the court limited that definition to material attached to the immediate container or otherwise expected to remain with the pesticide during the period of use. *Id.* at 119-20 (quoting letter from EPA's general counsel).

These decisions effectuate Congress’ purpose to have uniform labels on pesticides sold in interstate commerce, *see Allenby*, 958 F.2d at 944, without embracing broad preemption of a whole range of state regulation that was never contemplated by Congress. Both *Allenby* and *Jorling* distinguished between FIFRA labels, which are designed to reach the purchaser and often the end user, from warnings that directed to the general public or others who may encounter pesticides during or after their application. Given that nothing in FIFRA requires or prohibits such public or innocent bystander warnings, and FIFRA’s preemption is limited to “labeling,” states remain free to require such public notice as a condition of pesticide sale or use. Similarly, FIFRA cannot be read to preempt state failure-to-warn claims brought by such innocent bystanders.

Exercising their authority to regulate pesticide use, several states have adopted protective safeguards constraining pesticide applications around schools. Some states have required notification of students, teachers, and staff before pesticides are applied on school grounds. *See, e.g.,* Wyo. Stat. § 35-7-350 (72-hour advance notice of pesticide applications in school buildings or on school grounds and posting of signs around sprayed areas both before and after pesticide application); 302 Ky. Admin. Regs. 29:050, § 12 (24-hour notice of pesticide applications at

schools provided to children, teachers, or staff upon request); N.H. Code Admin. R. Pes 506.04 (permit required for aerial applications in residential areas, including schools, daycare centers, and hospitals, which cannot be granted before adjacent property owners receive notice and an opportunity to be heard). Other states have established a buffer zone around schools and other public buildings where aerial applications of pesticides are prohibited. 2 N.C. Admin. Code 09L.1005(b) (300-foot buffer around schools, hospitals, nursing homes, churches, and occupied buildings used for business or social purposes); N.J. Admin. Code § 7:30-10.6(q) (same); La. Admin. Code tit. 7, § 149(B) (1000-foot buffer around schools for aerial applications during school hours).

Such state regulation fills gaps in federal regulation of pesticide sale and use through EPA registration of pesticides. FIFRA expressly authorizes such state supplementation through affirmative state regulation. State damages actions similarly fill gaps left by FIFRA albeit indirectly. Because the registrant retains full authority and legal duties under FIFRA to ensure that its registrations and pesticide labels prevent unreasonable adverse health and environmental effects, state damages action promote the FIFRA scheme.

CONCLUSION

For the reasons set forth above, this Court should reverse the decision below and hold that FIFRA does not preempt state damage actions.