

No. 03-388

IN THE
Supreme Court of the United States

DENNIS BATES, ET AL.,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

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

**BRIEF OF AMICI CURIAE
NATURAL RESOURCES DEFENSE COUNCIL, ET AL.
IN SUPPORT OF PETITIONERS**

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40 C.F.R. § 166.25(b)	25
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42 Fed. Reg. 61,788 (Dec. 6, 1977)	22
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49 Fed. Reg. 28,666 (July 13, 1984)	18
49 Fed. Reg. 37,960 (Sept. 26, 1984)	11
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53 Fed. Reg. 15,956 (May 4, 1988)	10

59 Fed. Reg. 38,973 (August 1, 1994)	16
60 Fed. Reg. 17,357 (April 5, 1995)	16
66 Fed. Reg. 44,141 (Aug. 22, 2001)	26
67 Fed. Reg. 1919 (Jan. 15, 2002)	23
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3 Cal. Code. Reg. § 6400 14

302 Ky. Admin. Regs. 29:050, § 12 29

La. Admin. Code tit. 7, § 149(B) 29

N.H. Code Admin. R. Pes 506.04 29

N.J. Admin. Code § 7:30-10.6(q) 29

Wash. Admin. Code 16-228-1231(e) 15

MISCELLANEOUS

- DePalma, “When Pest Killers Make Mistakes,”
New York Times, Sept. 1, 2004 27
- Environmental Working Group and Healthy Building
 Network, *Poisoned Playgrounds* (2001) 18
- Fenske *et al.*, “Strategies for Assessing Children’s
 Organophosphorous Pesticide Exposures in
 Agricultural Communities,”
 10 *J. Expos. Anal. Evt’l Epid.* 662 (2000) 26
- General Accounting Office,
*Pesticides: EPA’s Formidable Task to Assess and
 Regulate Their Risks* (1986) 6
- Liptak, “The Poison is Arsenic, and the Suspect Wood,”
The New York Times, June 26, 2002 18
- Natural Resources Defense Council,
*Trouble on the Farm: Growing up with
 Pesticides in Agricultural Communities*,
 Oct. 1998 (available at [http://www.nrdc.org/health
 /kids/farm/farminx.asp](http://www.nrdc.org/health/kids/farm/farminx.asp)) 26
- Thompson, *et al.*, “Pesticide Take-Home Pathway Among
 Children of Agricultural Workers,”
 45 *J. Occ. Evt’l Med.* 42 (2003) 26

INTRODUCTION AND INTEREST OF AMICI¹

This brief addresses the issue of whether the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136 *et seq.*, preempts state damages actions arising out of personal injuries caused by exposure to federally registered pesticides. Amici are non-profit organizations dedicated to protecting individuals from harm relating to dangerous consumer products, including pesticides, and many have participated in regulatory proceedings concerning federal pesticide registration. Amici believe that FIFRA and state damages actions complement one another in a constructive way that strengthens the public health protection derived from pesticide regulation.

Natural Resources Defense Council is an environmental organization with more than 465,000 members nationwide. Its membership and staff of scientists, lawyers, and other environmental specialists have a longstanding interest in improving the regulation of pesticides and other toxic chemical residues in food, air, and water. NRDC has actively participated in the development, enforcement, and reform of pesticide laws and pesticide regulation for over two decades.

Public Citizen is an advocacy, lobbying, and litigating organization with 160,000 members nationwide. It has a longstanding interest in limiting the reach of the federal preemption doctrine to situations in which Congress clearly intends to oust state law in order to serve important federal objectives. Public Citizen’s lawyers have represented parties and amici before this Court in many cases that posed the

¹In blanket letters of consent filed with the Clerk, the parties have consented to the filing of amicus briefs in this case. Pursuant to this Court’s Rule 37.6, amici state that this brief was not authored in whole or in part by counsel for a party and that no one other than amici made a monetary contribution to the preparation or submission of this brief.

question whether federal law preempts state-law remedies intended to compensate those harmed by tortious conduct.

Trial Lawyers for Public Justice is a national public interest law firm dedicated to pursuing justice for the victims of corporate and governmental abuses. It seeks to ensure that tort law fully serves its dual purposes – compensating those injured by wrongful conduct and deterring similar conduct in the future. TLPJ is gravely concerned that, if the tort system is closed to innocent victims of improperly labeled pesticides through application of the preemption doctrine in this case, neither of these purposes will be served.

The Sierra Club is an environmental organization with over 700,000 members nationwide. It was one of the first organizations to advocate for laws protecting human health, wildlife, and the environment from the damage caused by pesticides.

Beyond Pesticides/National Coalition Against the Misuse of Pesticides has approximately 1,200 members nationwide. It promotes public and worker protection from pesticide hazards and the adoption of alternative pest management strategies that reduce or eliminate dependency on toxic chemicals. Beyond Pesticides has been an active participant in the regulatory process under FIFRA since its founding in 1981.

Defenders of Wildlife has over 450,000 members and supporters nationwide. It is dedicated to the protection of all native wild animals and plants in their natural communities. Defenders' programs focus on three serious threats to the planet: the accelerating rate of extinction of species; the associated loss of biodiversity; and the alteration and destruction of habitat.

Physicians for Social Responsibility is a national organization whose 30,000 members are physicians, other healthcare and public health professionals, and citizens concerned about threats to human health. It educates the medical community and the public about the links between

environmental exposures and human health and promotes preventive, precautionary policy solutions to protect public health. PSR has been an active participant in the regulatory proceedings under FIFRA.

The Farmworker Justice Fund, Inc. is an advocacy and education organization based in Washington, D.C. Its purpose is to empower migrant and seasonal farmworkers to improve their wages, working conditions, occupational safety, health, immigration status, and access to justice through litigation, advocacy, public awareness, capacity building, coalition building, and support for union organizing. For more than two decades, FJF has fought for improved protections for farmworkers and their families exposed to pesticides at home and on the job.

SUMMARY OF ARGUMENT

FIFRA charges registrants with ensuring that their pesticides 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. 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 liability similarly imposes obligations to ensure that product design and labeling will avoid unreasonable adverse health and environmental effects. State damages actions can identify shortcomings in previously approved FIFRA registrations and labels and prompt registrants to remain vigilant in ensuring that their products can be used without harming human health and the environment. Such actions create an incentive to avoid unreasonable harm and 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 ENVIRONMENTAL AND SAFETY RISKS.

A. FIFRA Imposes a Duty on Pesticide Registrants to Avoid Unreasonable Adverse Health and Environmental Effects At All Times.

Congress enacted FIFRA in 1947 to protect farmers from adulterated and ineffective pesticides. For over three decades, FIFRA had no health or environmental protections. In 1972 in the wake of Rachel Carson's *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 required EPA to 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 states and their subdivisions can supplement and make more stringent but cannot undercut. *See* 7 U.S.C. § 136v(a). A pesticide may generally not be sold or used in the United States unless it has an EPA registration for a specific use of the pesticide. *Id.* § 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. *Id.* § 136a(c)(5).

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. *Id.* § 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 meets FIFRA's standards. *Id.* §§ 136a(a), (c). 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 standards for the data required to support a pesticide registration. *See generally* 40 C.F.R. Part 152. The company seeking the registration (the "registrant") generates and submits the scientific studies on which EPA will base its determination. *Id.*

An EPA registration is 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 product as it moves through interstate commerce. A pesticide may not be used in a manner inconsistent with the label. 7 U.S.C. § 136j(a)(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 canceled 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, *Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks* at 3 (1986).

Congress amended FIFRA in 1988 and again in 1996 to impose deadlines on the reregistration process. Under the statutory timetable, EPA is not scheduled to complete the reregistration of all the old pesticides until fiscal year 2008. *See* 7 U.S.C. § 136a-1(g)(2)(A)(ii). Even when this initial reregistration process is complete, EPA will regularly need to revisit existing reregistrations to assess new data. It is common for a registration to identify gaps in data that the registrant must fill over time. For example, in 2000, EPA issued a conditional registration for Strongarm, the pesticide at issue in this case, that required the registrant to submit neurotoxicity, mutagenicity, and residue chemistry studies. <http://www.epa.gov/opprd001/factsheets/diclosulam.pdf>. While the studies were due in 2001, EPA has yet to complete its assessment and make revisions to the conditional registration. Similarly, under the 1996 Food Quality Protection Act, EPA must assess a food-use pesticide's potential to cause endocrine disruption effects and the cumulative effects of exposures to pesticides that have a common mechanism of toxicity, 21 U.S.C. § 3462(b)(2)(D)(v) & (viii), yet EPA is still in the process of developing protocols for assessing such effects. 67 Fed. Reg. 79,611 (Dec. 30, 2002) (requesting comment on EPA's proposed approach for screening for an

initial group of chemicals for effects on endocrine system). Likewise, EPA typically reregisters pesticides without first engaging in required consultations with the Fish and Wildlife Service and National Marine Fisheries Service to determine whether the pesticide use will jeopardize the survival of endangered species, as required under the Endangered Species Act (“ESA”), 16 U.S.C. § 1536(a)(2). See *Washington Toxics Coalition v. EPA*, No. C01-132C, Orders (W.D. Wash. July 2, 2002 & Aug. 8, 2003) (declaring EPA in violation of ESA for failing to consult on its pesticide registrations’ impacts on threatened and endangered salmon and ordering injunctive relief). Once EPA completes the ESA consultations, it will need to make changes to the registrations required to ensure that the pesticides will not cause jeopardy to endangered species’ survival.

Because EPA depends almost entirely on manufacturer submissions, and EPA does not itself conduct testing on the pesticides’ health and environmental effects, FIFRA imposes stringent and continuing obligations on registrants to submit complete, up-to-date information to EPA. First, a registrant may not knowingly falsify any part of an application for registration or other information required to be submitted under FIFRA and may not 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, even after EPA issues a registration based on the registrant’s submissions, the registrant has an ongoing obligation to provide EPA with all factual information that they have regarding unreasonable adverse health and environmental effects. *Id.* § 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. *Id.* §§ 136j(a)(1)(E), 136(q). Under FIFRA, “the burden is on the registrant to establish that continued registration poses no safety threat.” *Environmental Defense Fund v. EPA*, 510 F.2d 1292, 1302

(D.C. Cir. 1975).

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 subchapter.” 7 U.S.C. § 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. *Id.* § 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 and 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. Traditional state-law damages actions thus have historically provided the only means for compensating people who have been injured by unsafe or mislabeled pesticides.

Because cancellation proceedings are time-consuming and expensive, EPA rarely brings them to compel label changes. Rather, EPA leaves most use and label changes to its ongoing process of reregistering pesticides. However, as noted above, EPA has yet to reregister thousands of pesticides that were initially registered before Congress, in 1972, imposed stringent data requirements pertaining to human health 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 pesticides comply 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 meet 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. . . . With the limited government resources available to regulate a growing number of pesticide products, we believe that tort litigation can be an effective tool and ally to the regulatory process. If tort actions are not preempted by FIFRA, manufacturers' concern about possible tort liability may well lead them to take additional steps to provide users with information about their products. Such information could, in turn, enable users to choose and use pesticides in ways that are safer for themselves, others, and the environment.

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, *see* 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. *See* 21 C.F.R. § 801.430(c) (specific tampon warning).

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. 15,952 (May 4, 1988).

FIFRA and EPA’s regulations establish certain minimum requirements for pesticide labels, such as the inclusion of certain terms to reflect acute poison risks. 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. 7 U.S.C. § 136a(c)(5).

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. *Id.* § 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. 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 subchapter.

7 U.S.C. § 136v(a). Through this provision, Congress expressly left room for state regulation 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 subchapter.

Id. § 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) (preemption provision’s reference to “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 common-law obligations generally do no such thing.

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”).² 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 COMMON-LAW OBLIGATIONS PARALLEL MANUFACTURERS’ DUTIES UNDER FIFRA, ENCOURAGE SPEEDIER FIFRA COMPLIANCE, AND PROMOTE FIFRA’S GOAL OF PROTECTING HEALTH AND THE ENVIRONMENT.

In *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), this Court held that FIFRA does not preempt local regulation of pesticide use. Although 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.” *Id.* at 613-14. The Court concluded that FIFRA’s specific grant of authority to states to

²The House passed the amendment offered by Representative Panetta, but the substitute measure that passed the Senate Forestry and Agriculture Committee did not contain that amendment. S. Rep. No. 511, 97th Cong., 2d Sess. (1982).

regulate pesticide sale and use “acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow pre-emptive overlap might occur.” *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 buttress 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 7 U.S.C. § 136v(a), 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. *See* S. Rep. No. 92-970, 92d Cong., 2d Sess. (1972), *reprinted in* 1972 U.S.C.C.A.N. 4092, 4111-12 (“Local governments could, however, prohibit or restrict the sale or use of pesticides within their jurisdiction.”). 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; Wis. Stat. § 94.707(1m). 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 (lindane); 3 Cal. Code. Reg. § 6400 (restricted use

pesticides); Wash. Admin. Code 16-228-1231(e) (restricting the use of numerous pesticides to protect groundwater); Iowa Code Ann. § 206.32 (chlordane); Md. Code Ann. Agric. § 5-210.5 (chlordane, heptachlor, aldrin and dieldrin); Minn. Stat. § 18B.115 (chlordane and heptachlor); Wis. Stat. § 94.707(a)-(b) (2-4-5 trichlorophenoxyacetic acid and silvex).

State authority to ban or restrict pesticide use in a regulatory capacity is similar to many types of state damages actions. Although 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. *See Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988) (“The effects of direct regulation on the operation of federal projects are significantly more intrusive than the incidental regulatory effects of such an additional award provision. Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers’ compensation award if an employee’s injury is caused by a safety violation. We believe Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.”) (citation omitted).

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 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.*, 2000 WL 1763212 (9th Cir. 2000). Ultimately, the cases 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 adverse 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 remanded the design defect claim for a new trial under a newly announced risk-utility test. *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 673 (Ga. 1994).

State damages actions play a particularly important role in promoting FIFRA's health and safety goals given the backlog in EPA reregistrations discussed above. And 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. Although pesticide registrations establish prohibitions on worker re-entry during specified 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 reregistration 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 and rely on state-law compensation systems to make them whole.

Not only is the reregistration 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 were 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 industry-sponsored consumer awareness program, in lieu of mandatory warnings. 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. Liptak, “The Poison is Arsenic, and the Suspect Wood,” *New York Times*, at A1, June 26, 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 from” 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. *Id.* 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. The common-law duties on which those allegations were based thus mimic the manufacturer's duties under FIFRA, which places the burden of testing, identifying, and labeling as to risks to people and the environment on the registrant.

Thus, the plaintiffs' claims arising from pesticide-related injuries are based on state-law duties that parallel requirements imposed under FIFRA. Like the "parallel" state claims held not preempted by the federal Medical Device Amendments, *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496-97 (1996), they are not "in addition to or different from" FIFRA's requirements within the meaning of 7 U.S.C. § 136v(b), and, therefore, are not preempted.

In *Jenkins v. James B. Day & Co.*, 634 N.E.2d 998 (Ohio 1994), the Ohio Supreme Court reached the same 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. § 1261. 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.” 634 N.E.2d at 1002.

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 consistent with FIFRA. 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 and that EPA will continue to assess and require revised labels after that. 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 sense for Congress to preempt state regulatory labeling requirements, while allowing state damage actions that challenge the adequacy of pesticide warnings. 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 label 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.

Indeed, this Court has repeatedly noted, in rejecting preemption of state damages claims, that Congress can

rationally preempt state regulatory efforts that conflict with the federal regulatory scheme regarding a particular product or industry, while allowing state damages actions arising from those regulated activities to go forward. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (preemption of state positive law, but not state common law “does not produce anomalous results. It would have been perfectly rational for Congress not to pre-empt common-law claims, which — unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims.”) (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)); *Cipollone*, 505 U.S. at 518 (“there is no general, inherent conflict between [express] federal preemption of state [regulatory] warning requirements and the continued vitality of state common-law damages actions”); *Goodyear Atomic*, 486 U.S. at 185-86 (“The effects of direct regulation ... are significantly more intrusive than the incidental regulatory effects of such an award provision. ...Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.”); *Silkwood*, 464 U.S. at 256 (despite federal preemption of state regulatory authority, state-law punitive damages awards not preempted even though “regulatory in the sense that a nuclear plant will be threatened with damages liability if it does not conform to state standards”).

State damages actions 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. App. 1968), involved a three-year-old boy's ingestion of a roach poison, which led to his death. The court 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 alleging fraudulent and negligent misrepresentation for 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 1977, EPA found that the fungicide benomyl caused unreasonable adverse effects based on, among other things, evidence of birth defects, including rats born without eyes or with very small eyes after in utero exposure to benomyl. 42 Fed. Reg. 61,788 (Dec. 6, 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 (Aug. 30, 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 (Oct. 20, 1982).

Over the years since, dozens of children in rural areas have been born 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).

Although EPA initially addressed the potential for birth defects from benomyl through label warnings, Dupont ultimately requested cancellation of all of its registrations and ceased production of benomyl in 2001, 67 Fed. Reg. 1919 (Jan. 15, 2002), and EPA thereafter issued a notice phasing out remaining uses of benomyl. 67 Fed. Reg. 46,900 (July 17, 2002). Under FIFRA, the states had the authority to ban use of benomyl on the ground that it could not be used, even with extensive warnings, without causing unreasonable adverse effects, such as birth defects. Thus, the states plainly had the lesser authority to provide damages awards on the ground that benomyl was misbranded.

C. State Damages Actions Complement and 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.

This case concerns such a gap in that EPA neither reviews nor makes finding concerning the efficacy of 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). 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, such as the claims made by respondent that led to damage to petitioners' crops.

Efficacy claims are not alone. EPA never passes on the unreasonable adverse effects of many pesticides either because the registrant has concealed information needed to make such an assessment or because FIFRA authorizes the pesticide use without such a finding. Even where EPA makes such a determination, it never purports to require notice to members of the public who unwittingly may find themselves exposed to pesticides wafting away from their targets and into unwelcome locations.

1. 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. *Id.* § 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. § 166.25(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. *Id.* at 538-40. 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.

2. EPA-Approved Labels Are Not Intended To Provide Warnings To The Public, As Opposed to the Purchaser or User, About the Risks Posed by Pesticides.

Although some failure to warn claims might spur the registrant to strengthen the warnings on the EPA-approved label, others such claims 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. Although 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 aerial 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, 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, 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); Natural Resources Defense Council, *Trouble on the Farm: Growing up with Pesticides in Agricultural Communities*, Oct. 1998 (available at

<http://www.nrdc.org/health/kids/farm/farminx.asp>). 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), including cases involving school children mistakenly sprayed by pesticides. *See, e.g., Henderson v. Dept. of Agriculture*, 875 P.2d 487, 488 (Or. App. 1994); DePalma, “When Pest Killers Make Mistakes,” *New York Times*, at B1, Sept. 1, 2004. 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, and, indeed, EPA does not regulate the relationship between pesticide registrants and members of the general public, who may be unwittingly exposed to pesticides applied in public places or that drift away from their intended site.

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)*.

The local ordinance at issue in *Wisconsin Public Intervenor* required the posting of placards on sprayed areas notifying the public of the pesticide application and any applicable re-entry periods. 501 U.S. at 603. This Court never suggested that such a public notice requirement might be barred by FIFRA’s express preemption provision.

In addition, two federal courts of appeals have explicitly distinguished between preempted pesticide labels, which go to the purchaser of the pesticide, and other permissible 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*, 506 U.S. 825 (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

are directed to the general public or others who may encounter pesticides during or after their application.³ 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; 302 Ky. Admin. Regs. 29:050, § 12; N.H. Code Admin. R. Pes 506.04. Other states have established a buffer zone around schools and other public buildings where aerial pesticide applications are prohibited. N.J. Admin. Code § 7:30-10.6(q); La. Admin. Code tit. 7, § 149(B).

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.

³*Allenby* and *Jorling* involved both the provision of information to purchasers and public notice. The point-of-sale warnings in *Allenby* and the customer disclosures in *Jorling* would reach the purchaser of the pesticide products or services, while point-of-sale warnings and public notices on places where pesticides had been applied would notify the general public. The courts of appeals did not distinguish between the recipients in holding that FIFRA does not preempt such off-label warnings.

CONCLUSION

The decision below should be reversed.

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