Case Nos. 19-16636, 19-16708

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

EDWIN HARDEMAN,
Plaintiff-Appellee/Cross-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellant/Cross-Appellee.

On Appeal from the United States District Court
for the Northern District of California,
Nos. 16-cv-00525 & 16-md-02741 (Chhabria, J.)

BRIEF OF PROPOSED *AMICI CURIAE* CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION, FARMWORKER ASSOCIATION OF FLORIDA, FARMWORKER JUSTICE, MIGRANT CLINICIANS NETWORK, PESTICIDE ACTION NETWORK, UNITED FARM WORKERS, AND UFW FOUNDATION IN SUPPORT OF PLAINTIFF-APPELLEE/CROSS-APPELLANT AND IN SUPPORT OF AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 29(a)(4)(A) and Fed. R. App. P. 26.1, *Amici* California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, Migrant Clinicians Network, Pesticide Action Network, United Farm Workers, and UFW Foundation each certify that they have no parent corporation and no publicly held corporation owns more than 10% of their stock.

STATEMENT OF *AMICI* INTEREST[1]

Amici are nonprofit organizations that, collectively, represent and partner with hundreds of thousands of farmworkers across the country to minimize exposures to dangerous pesticides. As the people on the front lines directly handling pesticides and plants sprayed with pesticides, farmworkers are exposed to pesticides more frequently and in greater concentrations than any other group. They also face the greatest health risks from exposures to pesticides.

Farmworkers depend on complete and accurate pesticide labels for instructions about how best to minimize pesticide exposures and warnings about the health consequences of exposures that do occur, including the potential for poisonings, cancer, and other illnesses. Too often, existing pesticide labels lack

[1] All parties have consented to the filing of this brief. No party's counsel authored any part of the brief. Neither did any party, any party's counsel, or any person other than *amici* and *amici*'s counsel contribute money intended to fund the preparation of this brief.

information necessary to help farmworkers understand the risks they face, to convince supervisors of the importance of facilitating compliance with directions for use, and to enable health care providers to make prompt and accurate diagnoses. *Amici* have an interest in ensuring that farmworkers have the information they need to protect themselves and their families from pesticides. When injuries occur as a result of deficient labels, *amici* have an interest in ensuring that farmworkers can access courts to seek redress, expose labeling deficiencies, and spur manufacturers to correct them.

Rooted in the farmworker movement of the 1960s, **California Rural Legal Assistance Foundation** ("CRLAF") is a rural justice center focused on serving farmworkers and low-wage rural workers, regardless of their immigration status. Through its Pesticide and Work Safety Project, CRLAF focuses on reducing agricultural work hazards and pesticide exposures. CRLAF regularly partners with other non-profit organizations to educate decision-makers and the public about the serious health risks associated with pesticide exposures.

Farmworker Association of Florida ("FWAF") is a Florida-wide, grassroots, community-based, nonprofit farmworker membership organization with over 10,000 Haitian, Hispanic, and African American members. Since 1983, FWAF has worked to build power among farmworkers and other rural low-income communities. FWAF partners with farmworkers and community-members as they

seek to confront and control the issues that impact their lives, including near-constant exposure to pesticides.

Farmworker Justice is a nonprofit organization that seeks to empower farmworkers to improve their living and working conditions, immigration status, health, occupational safety, and access to justice. Farmworker Justice recognizes that agriculture consistently ranks as one of the nation's most hazardous occupations, farmworkers have few federal workplace safety protections, and farmworkers face a heightened risk of pesticide poisoning. Accordingly, Farmworker Justice's Health Program focuses, in part, on minimizing exposures to toxic pesticides among farmworkers and their families. Farmworker Justice long has fought to preserve farmers' and workers' rights to recover for harms caused by pesticides, including by submitting a friend-of-the court brief to the U.S. Supreme Court in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005).

Migrant Clinicians Network ("MCN") is a nonprofit organization that works to increase access to quality health care and reduce health disparities for migrant farmworkers and other mobile underserved populations. To achieve these goals, MCN engages in research, develops appropriate resources, advocates for migrants and clinicians, engages outside partners, and runs programs that support clinical care on the front lines of migrant health. MCN has developed resources to help migrant and seasonal farmworkers protect themselves and their families from

exposure to pesticides and to educate clinicians and others about the recognition and management of pesticide exposures.

Pesticide Action Network ("PAN") North America works to create a just, thriving food system. PAN partners with consumer, labor, health, environment, and agriculture groups worldwide to challenge the global proliferation of pesticides, defend basic rights to health and environmental quality, and work to ensure the transition to a just food system. PAN recognizes that, for farmworkers, pesticide exposures come on top of other workplace problems, including intimidation, harassment, and wage theft; PAN works with farmworker advocates across the country to address all these issues.

Begun in 1962 by Cesar Chavez, Dolores Huerta, Gilbert Padilla, and others, **United Farm Workers** ("UFW") is the nation's first and largest farmworkers union. UFW works to protect farmworkers from occupational injuries, including injures caused by exposures to pesticides, and fights to ensure that farmworkers have access to courts. In addition, UFW champions legislative and regulatory reforms for farmworkers, covering issues such as pesticides, worker protections, and immigration reform.

UFW Foundation, a non-profit sister organization of UFW, is a Department of Justice-accredited immigration legal service provider that offers critical services and resources to farmworker and immigrant communities. UFW Foundation's

regional offices annually serve over 100,000 immigrants in leading agricultural regions with significant pesticide use. As a result, UFW Foundation is directly aware of the harms that pesticide misuse and exposure pose to the health, safety, and economic security of farmworkers who handle and apply pesticides, as well as their families.

FACTUAL BACKGROUND

In the United States, over two million farmworkers labor in an industry widely understood to be among the most hazardous. *See* Nat'l Ins. of Occupational Safety & Health, *Agricultural Safety*, https://www.cdc.gov/niosh/topics/aginjury/default.html. As the U.S. Environmental Protection Agency ("EPA") has acknowledged, "the diversity of [the farmworker population] and the tasks they perform makes it challenging to ensure that [they] . . . are adequately protected." EPA, Pesticides; Agricultural Worker Protection Standard Revisions, 80 Fed. Reg. 67,496, 67,502 (Nov. 2, 2015).

Indeed, farmworkers face significant social and economic disadvantages. Approximately 75 percent of farmworkers were born outside the United States, and 70 percent are not U.S. citizens. *See* JBS Int'l, *Findings from the National Agricultural Workers Survey (NAWS) 2015–16: A Demographic and Employment Profile of United States Farmworkers* i (2018) ("NAWS") https://www.doleta.gov/naws/research/docs/NAWS_Research_Report_13.pdf. On average, farmworkers

earn between $20,000 and $24,999 each year. *See id*. at iii. A full third have annual family incomes that fall below the poverty line. *See id*.

As EPA has recognized, "[farmworkers] are potentially exposed to a wide range of pesticides with varying toxicities and risks," and "there is strong evidence that [farmworkers] may be exposed to [these] pesticides at levels that can cause adverse effects." 80 Fed. Reg. at 67,498. Farmworkers may be exposed while mixing and applying pesticides, for example, through contact with pesticide residues on non-target surfaces, and while weeding, harvesting, and transporting pesticide-treated plants.

EPA estimates that about 1,800 to 3,000 acute pesticide exposure incidents occur each year at farms, nurseries, and greenhouses across the country. *See id*. at 67,498, 67,502. Although this estimate accounts for *some* underreporting, it is only an estimate; studies suggest that up to 90 percent of exposure incidents are never reported because workers often forgo treatment for fear of losing their jobs or being labelled "troublemakers," pesticide-related illnesses often are misdiagnosed, and even correctly diagnosed illnesses often are not added to a central reporting database. *See* EPA, Pesticides; Agricultural Worker Protection Standard Revisions; Proposed Rule, 79 Fed. Reg. 15,444, 15,449 (Mar. 19, 2014).

In addition, EPA's estimate excludes the difficult-to-quantify short- and long-term health problems that result from regular exposure to pesticides over

months, years, and decades. *See* 80 Fed. Reg. at 67,498. Peer-reviewed scientific literature links this regular exposure to a range of serious illnesses, including various forms of cancer. *See* 79 Fed. Reg. at 15,450.

Not only do farmworkers face serious health risks as a result of their exposure to pesticides, farmworkers' *families* experience similar risks too—even if they never set foot on farms or venture inside nurseries or greenhouses. Farmworkers' family members may be exposed to pesticides through contact with the residues that workers bring home on their bodies and clothing. *See* 80 Fed. Reg. at 67,502. In addition, farmworkers, their family members, and others may be exposed through "drift," or "the movement of pesticide dust or droplets through the air at the time of application or soon after, to any site other than the area intended." EPA, *Introduction to Pesticide Drift*, http://www.epa.gov/reducing-pesticide-drift/introduction-pesticide-drift. According to the National Institute for Occupational Safety and Health, nearly 3,000 pesticide poisoning cases associated with drift occurred in 11 states between 1996 and 2008; 14 percent of those cases involved children under 15 years of age. *See* Nat'l Ins. of Occupational Safety & Health, *Risk of Illness from Pesticide Drift Greatest for Agricultural Workers, Study Finds* (June 6, 2011), https://www.cdc.gov/niosh/updates/upd-06-06-11.html.

The health risks borne by farmworkers and their families are particularly concerning because many workers and their family members lack access to appropriate health care. *See*, *e.g.*, 80 Fed. Reg. at 67,502. Cost is often a significant barrier; only 47 percent of farmworkers have health insurance of any kind. *See* NAWS at iv. Language and cultural barriers exist as well; most health care providers lack the language skills and cultural competency necessary to treat farmworkers and their families. In addition, providers often lack complete and accurate information about the risks associated with exposure to certain pesticides, without which they cannot provide proper care.

Because farmworkers face disproportionate risks from pesticides, they are especially dependent on pesticide labels. Although labels are by no means sufficient to protect farmworkers from every pesticide-related illness, farmworkers with access to adequate labels are more likely to be aware of the risks they and their families face as a result of pesticide exposure. Supervisors with access to adequate labels are more likely to understand the importance of prescribed mitigation measures—and, therefore, more likely to facilitate adherence to those measures. And health care providers with access to adequate labels are more likely to have the information they need to provide timely and effective medical care. Without widespread access to adequate labels, farmworkers and others lose a vital tool for minimizing and mitigating pesticide exposures.

SUMMARY OF ARGUMENT

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") prohibits the sale of any pesticide product that causes unreasonable adverse effects to human health or the environment. Where use of a pesticide can avoid such effects, the manufacturer, or "registrant," is charged with writing a product label that provides adequate warnings and directions for use. A pesticide is "misbranded" in violation of FIFRA if its label fails to provide adequate warnings or directions to protect people and the environment.

FIFRA establishes a fluid scheme that obligates manufacturers to provide the U.S. Environmental Protection Agency ("EPA") with new information about a pesticide's adverse effects, such its potential to cause cancer, as that information emerges. FIFRA also obligates manufacturers to revise pesticide labels as necessary to ensure that they *continue to provide* adequate warnings and directions for use to protect people and the environment from newly identified unreasonable adverse effects. A manufacturer who fails to make necessary revisions is liable for misbranding.

In *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), the U.S. Supreme Court held that states may provide additional remedies for FIFRA violations. When injuries occur as a result of deficient labels, state tort actions can help to expose the labeling deficiencies and spur manufacturers to correct them. The mere

possibility of state tort actions may encourage manufacturers to revise pesticide labels proactively, as FIFRA intends.

A pesticide's label is *not* the law. It is the vehicle for the manufacturer to provide purchasers and users with the warnings, directions for use, and other information they need to avoid unreasonable adverse effects to health and the environment. The label seeks to ensure that use of a pesticide will meet FIFRA's standards based on the information available at a particular moment in time. EPA's approval of a pesticide label provides no defense to any alleged FIFRA violation. Indeed, in registering pesticide uses and approving pesticide labels, EPA often overlooks the potential for many types of harm, such as endocrine-disrupting or hormone-mimicking effects, neurodevelopmental harm to children at low levels of exposure, and harm to bystanders from pesticide drift. EPA's approval of a label in the face of these significant gaps cannot be equated with a finding that the label is adequate to protect the health and environment from every type of harm. State damage actions can identify deficiencies in previously approved FIFRA labels based on emerging science and unaddressed harms and prompt manufacturers to remain vigilant in ensuring their products can be used without harming people and the environment.

ARGUMENT

I. FIFRA PLACES THE BURDEN ON PESTICIDE MANUFACTURERS TO ENSURE THEIR LABELS ARE AT ALL TIMES ADEQUATE TO PROTECT HEALTH AND THE ENVIRONMENT.

A. Manufacturers Must Craft Pesticide Labels To Comply With FIFRA's Protective Health Standard.

As enacted in 1947, FIFRA lacked health and environmental protections. In 1972, in the wake of Rachel Carson's *Silent Spring*, which documented damage to the environment caused by the pesticide DDT, Congress overhauled FIFRA to make the avoidance of "unreasonable adverse effects" its centerpiece. *See* Pub. L. No. 92-516, 86 Stat. 996 (1972); H.R. Rep. No. 511, 92d Cong., 1st Sess. (1971). As amended, FIFRA prioritizes health and the environment, and farmers and farmworkers are "the most obvious object of [its] protection." *Organized Migrants in Cmty. Action, Inc. v. Brennan*, 520 F.2d 1161, 1168–69 (D.C. Cir 1975) (quoting S. Rep. No. 92-838, at 43–44 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 4063); *see also* EPA, Worker Protection Standard, 57 Fed. Reg. 38,102-01, 38,103 (Aug. 21, 1992) ("The legislative history of the 1972 amendments indicates an express intent of Congress that farmers, farmworkers, and others be afforded . . . protection under FIFRA.") (citing S. Rep. No. 92-883, (Part II), 92nd Congress, 2d Session at 43–46 (1972)).

Under FIFRA, EPA must register a pesticide in order for the pesticide to be used in the United States. *See* 7 U.S.C. § 136a(a). To obtain a registration, which

is essentially a license, the manufacturer must submit animal laboratory studies that it has conducted according to EPA protocols. *See* 7 U.S.C. § 136a(a) and (c); *see also* 40 C.F.R. §152.42; 40 C.F.R. § 152.50(f)(3). If EPA finds that the pesticide meets FIFRA's "no unreasonable adverse effects" standard, it can register the pesticide for particular uses.

FIFRA charges the manufacturer, not the government, with devising a pesticide label that conveys adequate warnings and directions for use to protect health and the environment. *See* 7 U.S.C. § 136a(c)(1)(C); *see also* 40 C.F.R. § 152.50(e). Once approved by EPA, the label accompanies the product as it moves through interstate commerce. While the label is uniform, meaning the same label is used throughout the country, it can specify different warnings and directions for different areas based on local conditions. FIFRA makes it unlawful to use a pesticide in a manner inconsistent with its label. *See* 7 U.S.C. § 136j(a)(2)(G).

A pesticide label is not merely a sticker affixed to the pesticide container. Instead, the label is typically a lengthy brochure, providing warnings and directions for use for each crop and each application method. The nearly 50-page label for the insecticide Lorsban is illustrative. *See* EPA, Pesticide Product Label, LORSBAN-4E (Sept. 30, 2013)("Lorsban Label"), https://www3.epa.gov/pesticides/chem_search/ppls/062719-00220-20130930.pdf. That label warns users

to avoid contact between the insecticide and skin, eyes, or clothing; identifies required protective clothing and equipment; and details additional safety recommendations, such as the suggestion to "[w]ash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." *Id*. at 2–3. It provides first aid instructions to be followed if Lorsban touches a user's eyes, skin, or clothing. *See id*. at 5–6. And it provides detailed directions for use, specifying how much of the pesticide may be applied to each crop for which it is registered, including apples and corn, for example. *See id*. at 21–52. Although the Lorsban label applies nationwide, it includes certain state-specific restrictions. *See, e.g.*, *id*. at 14 (explaining that Lorsban should not be "aerially appl[ied] in Mississippi").

B. Manufacturers Have An Ongoing Duty To Update Their Labels And Are Liable For Misbranding If Their Labels Are Not Adequate To Protect Health And The Environment.

Once approved, a pesticide label is not forever static. To the contrary, FIFRA contains several provisions designed to ensure that the manufacturer will keep EPA apprised of new information regarding the pesticide's unreasonable adverse effects on health and the environment and will update the pesticide's label accordingly. First, FIFRA imposes on manufacturers an ongoing obligation to provide EPA with all factual information they acquire regarding pesticides' adverse effects on health and the environment. *See* 7 U.S.C. § 136d(a)(2); *see also* 40 C.F.R. pt. 159.

Second, FIFRA does not allow manufacturers to rely on the fact that EPA has registered a pesticide as "a defense for the commission of any offense" under FIFRA, including an EPA action to cancel the pesticide registration or a violation of FIFRA's misbranding provision. 7 U.S.C. § 136a(f)(2). FIFRA defines the term "misbranded" to encompass many potential flaws. *See* 7 U.S.C. § 136(q). For example, FIFRA provides that a pesticide is misbranded if its label does not conform to specific requirements governing the location of the ingredient statement and, for highly toxic pesticides, the inclusion of the skull and crossbones and the word "poison" in red. *Id*. § 136(q)(2)(A), (D). FIFRA also provides that a pesticide is misbranded if its label does not contain warnings and directions for use that are "adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(F)–(G).

Third, FIFRA imposes on manufacturers a continuing obligation to ensure that pesticide labels comply with FIFRA's requirements. *See* 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. Def. Fund v. EPA*, 510 F.2d 1292, 1297, 1302 (D.C. Cir. 1975); *see* 40 C.F.R. § 164.80 (providing that the registrant bears burden of persuasion in cancellation hearings); *see also* 110 Cong. Rec. 2948-49 (1964) (Rep. Sullivan) ("The burden of proof of safety should always be on the manufacturer . . . 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, a manufacturer must update a pesticide label as necessary to provide additional warnings or directions for use to protect health or 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]." 7 U.S.C. §§ 136a(f)(1); 136a(c)(5).

II. FIFRA'S PREEMPTION PROVISION AND SUPREME COURT PRECEDENT ALLOW STATES TO PROVIDE ADDITIONAL REMEDIES FOR VIOLATING FIFRA'S MISBRANDING STANDARDS.

This case is controlled by FIFRA's preemption provision, as construed by the Supreme Court in *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), and *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005). Together, these authorities confirm that states retain the power to regulate pesticide use, and states may provide additional remedies for violations of FIFRA's requirement that pesticide labels provide adequate warnings and directions to protect health and the environment.

A. States Retain The Authority To Add Use Restrictions.

FIFRA establishes a cooperative federalism scheme under which states are free to restrict and even ban federally approved pesticides. This is made explicit in FIFRA's preemption provision, which provides:

> 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). Through this provision, Congress expressly made it plain that FIFRA leaves room for supplemental state requirements that afford more, but not less, health and environmental protection.

FIFRA's preemption provision then 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).

The Supreme Court in *Mortier* held unanimously that, although "the 1972 amendments turned FIFRA into a 'comprehensive regulatory statute,'" FIFRA "leaves substantial portions of the field vacant" and, therefore, does not preempt state or local regulation of pesticides. *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), 501 U.S. at 613–14 (quoting *Ruckelshaus v. Monsanto*, 467 U.S. 986, 991 (1984)). Instead, FIFRA's specific grant of authority to states "acts to ensure that the States could continue to regulate [pesticide] 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.

States have exercised this authority by banning the use of EPA-registered pesticides in their states. *See, e.g.*, S.B. 3095 S.D. 1 H.D. 1 C.D. 1, 29th Leg.

(Haw. 2018). And a state's decision to ban a pesticide can inform EPA's assessment of whether that pesticide causes unreasonable adverse effects. For example, Washington State banned the highly toxic pesticide Phosdrin after it poisoned 29 workers in the state in a matter of months. The following year, EPA found that Phosdrin caused unreasonable adverse effects to workers, and the manufacturer voluntarily cancelled Phosdrin's registrations. *See* EPA, Notice of Receipt of Request for Cancellation, Announcement of Cancellation Order, and FIFRA Section 6(g) Notification for Mevinphos, 59 Fed. Reg. 38,973-02 (Aug. 1, 1994); *see also* EPA, Mevinphos; Amendment to Cancellation Order and FIFRA Section 6(g) Notification, 60 Fed. Reg. 17,357-02 (Apr. 5, 1995).

B. States Can Provide Additional Remedies For Violations of FIFRA's Standards.

Bates built on *Mortier* by making clear that states retain authority to provide additional remedies for FIFRA violations through state actions for damages, as well as through state laws and regulations. In particular, *Bates* held that nothing in FIFRA "would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law." *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 442 (2005). Imposing these additional sanctions—whether through state legislation or regulation or through state tort liability—would not equate to imposing requirements "in addition to or different from" federal labeling

requirements.

As *Bates* made clear, a state's authority to impose additional sanctions extends even to violations of FIFRA's misbranding provision. Indeed, *Bates* specifically addressed FIFRA's misbranding standard, stating that a labeling requirement imposed through state common law, including failure to warn liability, is not preempted "if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id*. at 447; *accord id*. (holding that "state law need not explicitly incorporate FIFRA's standard as an element of a cause of action in order to survive pre-emption").

Bates viewed state remedies that enforce federal misbranding requirements "to aid, rather than hinder the functioning of FIFRA." *Id*. at 451. Such remedies help to ensure that manufacturers will revise pesticide labels as necessary to protect people and the environment from newly identified unreasonable adverse effects, just as FIFRA intends. *See id*.

Rumsey v. Freeway Manor Minimax, 423 S.W.2d 387 (Tex. Civ. Appeals Ct. 1968), is illustrative. In that case, the Texas Court of Appeals upheld a finding of negligence after a three-year-old boy died as a result of coming into contact with an insecticide for which there was no antidote. Even though the insecticide's label "was approved by the appropriate agencies," the court nonetheless concluded that the manufacturer had been negligent in failing to disclose the lack of an antidote on

the insecticide's label. *Id*. at 394. *Rumsey* predates FIFRA's focus on health and the environment, but it supports the goals of the amended Act by incentivizing manufacturers to ensure that labels disclose the *full* range of risks associated with pesticide use. Indeed, the specter of damage actions may provide manufacturers with economic incentives to stay abreast of possible injuries from use of their pesticides and make needed label changes proactively, before any injuries occur. *See* 544 U.S. at 451.

III. EPA'S AUTHORITY TO APPROVE LABEL CHANGES DOES NOT PREEMPT STATE TORT LIABILITY.

The United States and Monsanto argue that the fact that EPA must approve significant label changes preempts any state liability for failing to provide different label warnings or directions for use. The United States goes so far as to claim that "the label is the law" and, as a result, states cannot establish liability based on its contents or omissions. This is absurd. If followed to its conclusion, this argument would lead to the preemption of any tort claim challenging the adequacy of an EPA-approved label, even if that label plainly violates FIFRA's requirements. This outcome is foreclosed by *Bates*.

A. States Can Provide Remedies That Lead To Changes In EPA-Approved Labels In Order To Avoid Misbranding.

Although FIFRA preempts states from imposing different labeling *requirements*, as *Bates* held, it leaves states free to establish additional *remedies*

for violating FIFRA's misbranding provision and other requirements. State tort liability is a permissible additional remedy. Even if state tort liability *induces* a pesticide manufacturer to change its label, that change is a voluntary response by the manufacturer, not a state-imposed requirement that could be preempted under FIFRA. *See* 544 U.S. at 445–46. Indeed, the manufacturer could respond to its liability in many ways including, for example, by ending the offending use, adding warnings, or requiring mitigation measures. Spurring the manufacturer to take any of these actions furthers FIFRA's goal of protecting health and the environment. The Supreme Court did not view EPA to have a gatekeeper role, allowing it to dictate how a manufacturer should respond to a jury verdict or precisely how it should change its label to comport with a state standard of care that parallels FIFRA's legal standards. *See id*. at 436, 438, 439.

By arguing that "the label is the law," EPA is asserting that it is the label that establishes the legal standard of conduct under FIFRA. That is incorrect. FIFRA's misbranding provisions establish the legal standard. The label is merely the manufacturer's attempt to meet FIFRA's requirements, as applied to that particulate pesticide, by conveying to purchasers and users warnings and directions for use that are adequate to protect health and the environment. Violating the label is an offense under FIFRA, but that does not make the label a legal standard with preemptive effect. Indeed, the fact that EPA has registered a pesticide use and

approved a pesticide label is no defense to *any* violation of FIFRA. *See* 7 U.S.C. § 136a(f)(2). If EPA approved a label that lacks adequate warnings or directions for use to protect health or the environment, the pesticide is misbranded, and EPA's approval does not immunize the manufacturer from liability.

B. EPA Has No Monopoly On Determining What Constitutes Misbranding.

EPA is not the sole determinant of what constitutes misbranding. In *Bates*, the United States argued that states could not impose failure to warn liability "absent an EPA finding of misbranding." Brief for the United States as Amicus Curiae Supporting Respondent at 25, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005)(No. 03-388), 2004 WL 2681684. Similarly, Dow warned that state juries might conclude that pesticides are misbranded even if EPA already had rejected such claims, and EPA thus might be compelled to approve a label warning with which it disagreed. *See* Brief of Respondent at 37–38, 41–42, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005)(No. 03-388), 2004 WL 2758217("Dow Brief"). The Supreme Court rejected these arguments.

As *Bates* recognized, "juries are in no sense anathema to FIFRA's scheme: In criminal prosecutions for violation of FIFRA's provisions, . . . juries necessarily must pass on allegations of misbranding." 544 U.S. at 452 (internal citation omitted). EPA also has authority under FIFRA to issue stop sale or use orders, initiate cancellation proceedings, and seek civil penalties for misbranding and other

violations of FIFRA. *See* 7 U.S.C. §§ 136d (cancellation proceedings), 136k(a) (stop sale or use orders), 136l (civil or criminal penalties). Each of these actions either proceeds through or can be challenged in administrative and/or judicial proceedings. In such proceedings, administrative law judges and courts may disagree with EPA's application of FIFRA's misbranding requirements to a particular label and overturn its action.

FIFRA allows states to assume primary enforcement authority for pesticide use violations upon EPA approval of the state's pesticide use laws and enforcement and recordkeeping procedures. *See* 7 U.S.C. § 136w-1(a). Once EPA delegates primary enforcement authority to a state, as it has to California, the state can bring actions to cancel registrations of pesticides. *See*, *e g.*, Cal. Food & Agric. Code §§ 12824 & 12825 (providing that California can cancel registrations of pesticides that have "demonstrated serious uncontrollable adverse effects," are "detrimental . . . to the public health and safety," or are misbranded). When a state exercises its enforcement authority, state courts or administrative tribunals decide whether cancellation is appropriate.

Thus, despite the United States' and Monsanto's contentions to the contrary, EPA has no monopoly on deciding whether a pesticide is misbranded. Its approval of pesticide labels has no preclusive effect on state actions to prevent misbranding and enforce other requirements.

C. EPA's Approval Or Disapproval Of A Label Has No Preemptive Effect.

Both Monsanto and the United States contend that EPA can effectively preempt state tort liability by disapproving a label change, as it has purported to do with a letter disapproving of California's state law warnings for glyphosate. EPA's action on a requested label change, however, has no preemptive effect.

In *Bates*, Dow argued that allowing juries "to give content to FIFRA's misbranding prohibition" would "establish[] a crazy-quilt of anti-misbranding requirements." Dow Brief at 16. In trying to make the case for conflict preemption, it argued that a state jury verdict would require a change in the label, but such a change cannot be made without EPA permission. *See* Dow Brief at 37. Dow elaborated:

> If a different jury were to reject similar challenges to the same label, . . . that result would indicate that there was no basis for EPA to approve any change to the label. Moreover, EPA might well not agree with the judgment that the labeling change effectively required by the adverse jury verdict was appropriate. Manufacturers therefore could quickly find themselves in conflicting positions vis-à-vis both state and federal law.

Id.

In rejecting this argument, *Bates* found no evidence that state tort suits had produced a crazy quilt of requirements or that they would pose difficulties beyond those manufacturers regularly experience due to the risk of competing jury verdicts. *See* 544 U.S. at 451–52. And if issues arose, EPA could respond by

promulgating regulations that refine FIFRA's general misbranding prohibitions. *See id*. at 453 & nn. 27–28. The Court pointed out that EPA regulations give content to some of FIFRA's misbranding prohibitions by, for example, requiring use of the word "caution" instead of "danger," but they simply reiterate FIFRA's broadly phrased requirements to have warnings and directions for use that are adequate to protect health and the environment. *See id*. at 453 & n.28. This remains the case.

While regulations promulgated pursuant to EPA's delegated authority have the force of law and preemptive effect under the Supremacy Clause, *see, e.g.*, *City of New York v. Fed. Commc'n Comm'n*, 486 U.S. 57, 63–64 (1988), EPA's approval or disapproval of a label change does not for at least three reasons. First, to have preemptive effect, an agency action must interpret the controlling law by addressing an ambiguity or filling in a gap in the statute. *See U.S. v. Mead Corp.*, 533 U.S. 218, 226–27, 229 (2001); *see also Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) (explaining that, to have preemptive effect, the agency must act "pursuant to the gap-filling power delegated to it by Congress," and its action must carry the force of law under *Mead* and its progeny). A label approval is not an authoritative and general interpretation of FIFRA. Rather, it is an application of FIFRA's misbranding requirements to a particular set of facts, and as a result it has no preemptive effect. *See id*. (explaining that agency enforcement

guidelines set out in a letter have no preemptive effect); *see also Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 251–52 (3rd Cir. 2008) (finding that an FDA advisory addressing some risks from methylmercury in tuna did not preempt state tort claim challenging failure to include warnings on tuna products); *id.* at 254–55 (concluding that an FDA letter deciding not to require warnings did not preempt failure to warn claims).

Second, to have preemptive effect, the agency must act pursuant to delegated statutory authority and conform to governing procedural requirements. *See* 486 U.S. at 63–64. EPA has express authority to promulgate regulations interpreting FIFRA, which can have preemptive effect if EPA complies with specific notice-and-comment rulemaking and consultation requirements. *See* 7 U.S.C. § 136w-1. But EPA is not acting pursuant to this authority or in accordance with the required procedures when it approves or disapproves a label. Although EPA's labeling decisions can be challenged in court, *see* 7 U.S.C. § 136n, that fact alone is insufficient to give label approvals preemptive effect.[2]

Third, in acting on a proposed label change, EPA must follow prescribed procedures and adhere to FIFRA's requirements. Under FIFRA, EPA must have

[2] Monsanto's reliance on *Reckitt-Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1138 (D.C. Cir. 2010), is unavailing, because that case held only that a certain EPA interpretation was ripe for judicial review, not that it had preemptive effect.

before it a proposed label, including the warnings and directions for use that the manufacturer seeks to add. *See* 7 U.S.C. § 136a(c)(1)(C). EPA must approve the label change if it determines the proposed label will not violate FIFRA. 7 U.S.C. § 136a(f)(1). And its action must be reasonable, meaning not arbitrary, capricious, or in violation of the governing statute. *See* 533 U.S. at 227, 229; *see also Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1047 (9th Cir. 2008) (explaining that courts can set aside EPA pesticide actions if they are arbitrary, capricious, or not in accordance with FIFRA).

EPA's action on the proposed label change must be based on the evidence before it. For example, Monsanto could have drafted a label explaining that EPA and the International Agency for Research on Cancer ("IARC") have reached different conclusions with respect to glyphosate's carcinogenicity and providing directions for use that would minimize the type of exposures that could lead to cancer. With the proposed label before it, EPA could evaluate whether the label would be false or misleading and whether the directions for use would be adequate to protect health. However, EPA has no authority to disapprove label changes simply to immunize manufacturers from tort liability for violating standards of care that parallel FIFRA's misbranding prohibitions. *Bates* held that FIFRA preserves state authority to provide additional remedies for misbranding. EPA cannot override that authority by withholding its approval for label changes precipitated

by such jury verdicts.

IV. EPA'S APPROVAL OF A MANUFACTURER'S PROPOSED LABEL OFTEN FAILS TO ADDRESS IMPORTANT HEALTH RISKS, AND TORT LIABILITY CAN INDUCE THE MANUFACTURER TO FILL THE GAPS.

It is often the case that EPA's registration of a pesticide and approval of the manufacturer-drafted pesticide label overlook serious harms that later emerge. For example, EPA never passed on the accuracy of the label statement at issue in *Bates*, which represented that the pesticide could be used in all areas where peanuts are grown. While *Bates* acknowledged that EPA's review of pesticide efficacy had been waived, *see* 544 U.S. at 440, its holding that FIFRA does not preempt state remedies for violating FIFRA's misbranding standard is in no way limited to efficacy claims, *id*. at 447–49, contrary to Monsanto's assertion. *See* Monsanto Br. at 30. Indeed, EPA's misbranding regulations expressly prohibit false and misleading statements about a pesticide's effectiveness. *See* 40 C.F.R. § 156.10(a)(5)(ii). And, under *Bates*, states can provide additional remedies for violations of this prohibition.

Here, EPA conducted a registration review of glyphosate, the active ingredient in Roundup. Its conclusions about carcinogenicity and recent letter about cancer warnings pertain only to glyphosate. But Roundup contains other chemicals in addition to glyphosate. This is commonplace. Inert ingredients make up the bulk of most pesticide product formulations, and many such inert

ingredients are listed as hazardous chemicals by EPA and other federal agencies under statutes regulating exposure to toxic chemicals. While EPA has the authority to require pesticide labels to disclose the presence of such hazardous inert ingredients, it has not done so for every pesticide product. *See Ctr. for Envtl. Health v. McCarthy*, 192 F. Supp. 3d 1036, 1039, 1042, 1044 (2016). Hardeman introduced evidence that Roundup is more carcinogenic than glyphosate alone. If so, Hardeman's state damages action could serve an important gap-filling purpose by prompting Monsanto to update the Roundup label so that it properly discloses the risks associated with use of Roundup—not just its active ingredient.

EPA often misses significant health risks in its reviews of pesticides and pesticide labels. Recognizing that EPA's registration of a pesticide is no guarantee against unreasonable adverse effects, FIFRA has mechanisms to gather additional information and requires EPA to conduct additional reviews both in response to petitions presenting new evidence of harm and as a matter of course for each pesticide every 15 years. *See* 7 U.S.C. § 136a(g)(1)(A)(iii). The following examples are illustrative of gaps in protection left by existing registrations.

First, FIFRA allows EPA to conditionally register a pesticide pending submission of missing data. *See* 7 U.S.C. § 136a(c)(7). EPA has invoked this authority extensively to approve over half of consumer and agricultural products. NRDC, *Superficial Safeguards: Most Pesticides Are Approved by Flawed EPA*

Process (2013), https://www.nrdc.org/sites/default/files/flawed-epa-approval-process-IB.pdf. Obviously, EPA has not yet passed on the missing data when it conditionally registers a pesticide and approves the pesticide label. As a result, EPA may be unaware of the full range of adverse effects associated with conditionally registered pesticides. *See Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015) (vacating EPA's unconditional registration of sulfoxaflor because EPA had failed to obtain the studies on sulfoxaflor's toxicity to bees that it had deemed necessary when it conditionally registered the pesticide).

Second, Congress has directed EPA to keep abreast of emerging health risks, but EPA's progress is often slow. For example, in 1996, Congress directed EPA to assess the potential for food-use pesticides to cause endocrine-disrupting—that is, hormone-mimicking—effects. *See* 21 U.S.C. § 346a(b)(2)(D)(viii). EPA re-registered older pesticides in 2006 without obtaining the required studies, and it is still in the midst of the screening process. *See* EPA, *Endocrine Disruptor Screening Program Timeline*, https://www.epa.gov/sites/production/files/2016-04/documents/edsp-timeline-042016.pdf.

Third, farmworkers and others filed a petition asking EPA to establish no-spray buffers around schools, homes, and other places people gather for two classes of neuro-toxic pesticides because general label instructions to avoid allowing the pesticides to contact people had failed to prevent acute poisonings

from pesticide drift. In response to the petition, EPA acknowledged its legal obligation to address pesticide drift and provide more specific safeguards, but indicated it would do so in its reviews of individual pesticides. *See* Agency Response to Pesticides in the Air – Kids At Risk: Petition to EPA to Protect Children from Pesticide Drift (Mar. 31, 2014), www.regulations.gov at EPA-HQ-OPP-2009-0825-0084. To date, EPA has approved label changes establishing no-spray buffers around homes, schools, hospitals, day cares, parks, and other places people gather for *only one* of the pesticides. *See* Lorsban Label at 15.

Fourth, a 2007 petition sought to protect children from the pesticide chlorpyrifos based on a growing body of published peer-reviewed science correlating learning disabilities and permanent damage to children's brains with exposures to chlorpyrifos. Upon reviewing the science, EPA concluded that chlorpyrifos damages children's brains, and the current registrations and labels fail to prevent this harm.[3] EPA proposed to end food uses of chlorpyrifos in 2015.[4] However, EPA has yet to change the registrations or require label revisions adequate to protect health and the environment. EPA, Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35,555

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[3] *See, e.g.*, EPA, Revised Chlorpyrifos Human Health Risk Assessment (Dec. 29, 2014), www.regulations.gov at EPA-HQ-OPP-2008-0850-0195.
[4] *See* Proposed Chlorpyrifos Tolerance Revocation Rule, 80 Fed. Reg. 69,080 (Nov. 6, 2015).

(July 24, 2019) (postponing action to revoke tolerances and registrations for food uses of chlorpyrifos).

In short, EPA's approval of a label is confined to the information before it at the time of that approval, which often fails to capture the full range and nature of harm from the pesticide. And new information constantly emerges. People may be poisoned by a pesticide, studies may show that the pesticide causes cancer or neurodevelopmental harm, and air monitors or human experience may demonstrate the pesticide's propensity to drift in toxic amounts to homes and schools. While EPA has the authority and duty to review such evidence, its reviews are often slow, leaving people in harm's way for too long.

By design, however, EPA registration decisions and pesticide labels are not fixed for all time. FIFRA builds in feedback loops and ongoing duties. Manufacturers must submit adverse effects information, including information arising from litigation, *see* 40 C.F.R. § 159.160(c), and conduct further studies to address evolving science. And manufacturers have an ongoing duty to ensure that their labels provide adequate warnings and directions for use to protect health and the environment. State tort liability can add incentives to fulfill this obligation and afford farmworkers, their families, and others harmed by pesticides an avenue for relief where federal remedies fall short.

CONCLUSION

For these reasons, *amici* respectfully ask this Court to affirm the district court's ruling on preemption.

Respectfully submitted this 30th day of March 2020.

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CERTIFICATE OF COMPLIANCE

9th Cir. Case Number(s) 19-16636, 19-16708

I am the attorney or self-represented party.

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