Nos. 19-16636, 19-16708

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 FOR *AMICI CURIAE* PUBLIC LAW SCHOLARS IN SUPPORT OF PLAINTIFF-APPELLEE

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IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici are law professors whose teaching and scholarship have addressed federal preemption of state law.[1] Our scholarly interest in preemption arises from teaching and writing in a variety of related fields, including administrative law, constitutional law, environmental law, health law, and torts. William W. Buzbee is a Professor of Law at the Georgetown University Law Center. Daniel Farber is the Sho Sato Professor of Law at the University of California, Berkeley School of Law. Daniel A. Lyons is a Professor of Law at Boston College Law School. Thomas O. McGarity holds the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas School of Law. Paul McGreal is a Professor of Law at Creighton University School of Law. David Rubenstein is a Professor of Law at Washburn University School of Law. Ernest A. Young is the Alston & Bird Professor at Duke Law School.

Each of us joins this brief solely in our individual capacity as lawyers and scholars, and the views expressed here should not be attributed to our institutions. Aside from the issues raised by Monsanto's preemption defenses, *amici* express no

[1] This brief has been filed with the written consent of the parties. Pursuant to FED. R. APP. P. 29(c), counsel for *amici* affirm that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amici* or their counsel, make a monetary contribution to the preparation or submission of this brief.

view as to Plaintiff Edwin Hardeman's claims on the merits or any other matters raised in this case.

SUMMARY OF ARGUMENT

Courts must honor the *limits* of Congress's preemptive intent no less than its intent to require uniformity on certain points. The text of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v, explicitly preserves broad state regulatory authority over pesticides and confines federal preemption to a relatively narrow scope. And the Supreme Court's authoritative interpretation of that text in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), confirms both the narrow meaning of FIFRA's uniformity provision and, as a general interpretive matter, a court's "duty to accept the reading that disfavors pre-emption." *Id.* at 449.

Binding Supreme Court precedent establishes two propositions that govern resolution of this appeal. First, *Bates* held that FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation," *id.* at 450, including not only the authority to enforce labeling requirements "equivalent to, and fully consistent with, FIFRA's misbranding provisions," *id.* at 447, but also the right to "ban or restrict the uses of pesticides that EPA has approved," *id.* at 450. *Bates* thus forecloses Monsanto's core argument that EPA's decision to approve Roundup's label without a cancer warning in itself preempts further state imposition of common law duties to warn of cancer risks.

Second, a line of cases culminating in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), has emphasized that federal agencies may act to preempt state regulation only where Congress has delegated an agency authority to act with the force of law, and the agency acts pursuant to that authority. In this case, Monsanto relies on a letter from an EPA administrator and certain other statements by the agency to establish preemption of the common-law duties asserted by Hardeman's suit. These actions plainly do not amount to action with the force of law, and they therefore cannot establish preemption of Hardeman's claims.

Finally, Monsanto's broad vision of federal preemption under FIFRA should be viewed in a broader constitutional context. Because Congress's enumerated powers are so expansive under contemporary doctrine, preemption has become the central problem of American federalism. The primary constraints on preemption derive from the political representation of the States in Congress and the procedural difficulty of making supreme federal law. It is thus particularly important for courts to honor the intent of Congress where, as in FIFRA, Congress acts to preserve state law. And it is equally critical not to accord broad preemptive powers to federal agencies, which act outside the political and procedural safeguards of federalism.

ARGUMENT

I. EPA's Decision to Register Glyphosate and Approve Monsanto's Label Does Not Preempt State Failure-to-Warn Claims.

Monsanto seems to make two distinct preemption arguments. First, it asserts that EPA's approval of Roundup's label in itself preempts state-law claims for failure to warn. Second, it argues that EPA's statements concerning glyphosate in letters and "issue papers" have independent preemptive force. *Bates* forecloses the first argument; the second argument is barred by the Supreme Court's recent decision in *Merck*. We address the general approval argument in this Part, and the agency action argument in Part II, *infra*.

A. FIFRA Leaves Considerable Scope for State Law.

Section 136v(a) of FIFRA expressly acknowledges that a "State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter." 7 U.S.C. § 136v(a). In *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), the Supreme Court observed that FIFRA is not "a sufficiently comprehensive statute to justify an inference that Congress had occupied the field to the exclusion of the States." *Id.* at 607. "To the contrary, the statute leaves ample room for the States and localities to supplement federal efforts even absent the express regulatory authorization of § 136v(a)." *Id.* at 613.

FIFRA's § 136v(b) does forbid States to "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b). In *Bates*, the Supreme Court ascribed "a narrow, but still important, role" to this section: "In the main, it pre-empts competing state labeling standards—imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings—that would create significant inefficiencies for manufacturers. The provision also pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." 544 U.S. at 452. But *Bates* made clear that "the statute authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Id*. at 450.

Bates recognized four more specific aspects of the FIFRA regime that are of importance to this case. First, "States may ban or restrict the uses of pesticides that EPA has approved." 544 U.S. at 450 (citing 7 U.S.C. § 136v(a)). This express state authority to ban or restrict products that federal agencies have approved for market sets FIFRA apart from other regimes, such as those governing medical devices or prescription drugs, with an ostensibly similar structure of front-end federal approvals supplemented (or not) by back-end state common-law monitoring. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (medical devices); *Wyeth v. Levine*, 555 U.S. 555 (2009) (prescription drugs). Second, § 136v(b) does not foreclose a state role

with respect to product labeling; rather, "States have ample authority to review pesticide labels to ensure that they comply with both federal and state labeling requirements." 544 U.S. at 442. Third, Congress did not mean to foreclose "tort litigation against pesticide manufacturers," which was "a common feature of the legal landscape at the time of the 1972 amendments" to FIFRA. *Id.* at 440–41. Such remedies provide "a long available form of compensation" as well as "an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." *Id.* at 449–50. In the *Bates* Court's view, these "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA," especially because "FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings." *Id.* at 451. Fourth and finally, *Bates* explicitly embraced a presumption against preemption in FIFRA cases. 544 U.S. at 431 (citing, *inter alia, Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947)). Thus, the Court said that "[e]ven if Dow had offered us [an equally] plausible alternative reading of § 136v(b) . . . we would nevertheless have a duty to accept the reading that disfavors pre-emption." 544 U.S. at 449.

B. Approval of a Label Does Not Preempt State Failure-to-Warn Claims.

Monsanto claims that "[n]ational uniformity of pesticide labeling is a bedrock principle of FIFRA," Monsanto Br. at 25; emphasizes EPA's "comprehensive

control over the labeling of federally registered pesticides," *id.* at 27; and asserts that FIFRA "forbids states from adding labeling requirements," *id.* at 26. The company's claim seems to be that EPA's decision to approve Roundup's label and its various decisions regarding glyphosate are determinative. Monsanto asserts that FIFRA's pesticide labeling regime is equivalent to the regime for medical devices under the Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 360c *et seq.*, which requires "'a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.'" *See* Monsanto Br. at 31-32 (quoting *Riegel*, 552 U.S. at 323). According to Monsanto, FIFRA is "[m]uch the same": "When EPA approves pesticide labeling, it determines that *that labeling*, not labeling more aggressive or subdued, provides appropriate warnings, and a manufacturer may not change the labeling without prior EPA approval." Monsanto Br. at 32 (Monsanto's emphasis).

The analogy is a false one. Federal regulatory regimes differ considerably in their preemptive effect, both in their relevant textual provisions and in their authoritative constructions by the courts.[2] FIFRA—unlike the federal medical

[2] *See, e.g.*, Ernest A. Young, *"The Ordinary Diet of the Law": The Presumption Against Preemption in the Roberts Court*, 2011 SUP. CT. REV. 253, 303–04 & n.281

device regime—explicitly leaves states free to ban or otherwise restrict pesticides even after they are approved by a federal agency. *See* 7 U.S.C. § 136v(a); *Bates*, 544 U.S. at 450. Both FIFRA's uniformity section and the MDA's preemption provision bar state requirements that are "different from, or in addition to" federal mandates. *See* 7 U.S.C. § 136v(b); 21 U.S.C. § 360k(a)(1). But the MDA's provision applies to *all* state regulation of "the safety or effectiveness of the device or . . . any other matter included in a [federal] requirement," 21 U.S.C. § 360k(a)(2), while FIFRA's language governs only the pesticide's label, *see* 7 U.S.C. § 136v(b). *Bates* thus concluded that FIFRA's uniform labeling provision was primarily directed at preventing conflicting state requirements for "color, font size, and wording of warnings," 544 U.S. at 452, while leaving intact state authority to "ban or restrict the uses of pesticides that EPA has approved," to "register . . . pesticides for uses beyond those approved by EPA," or to enforce labeling requirements "equivalent to, and fully consistent with" FIFRA's rules, *id.* at 447, 450.

Likewise, because medical devices often enhance health and safety, human health concerns weigh on both sides of the scale concerning whether to allow additional state regulation. Hence, *Riegel* concluded that Congress deliberately

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(2012) (noting that the medical devices regime is more broadly preemptive than the regime for prescription drugs).

chose to foreclose compensation of injured persons through the state tort system in order to encourage the manufacture of federally approved devices. *Riegel*, 552 U.S. at 326. *Bates* interpreted FIFRA to embody a different choice. *See* 544 U.S. at 432–33.[3] The bottom line is that the Medical Devices Amendments are far more broadly preemptive than FIFRA, *compare* Riegel, 552 U.S. at 333 (Ginsburg, J., dissenting) ("The [MDA], as construed by the Court, cut deeply into a domain historically occupied by state law."), *with Bates*, 544 U.S. at 450 (FIFRA is "a relatively decentralized scheme that preserves a broad role for state regulation"), and *Bates* thus furnishes a far surer guide than *Riegel* for decision here.

In *Bates*, the Court made clear that it was considering both § 136v(b)'s express preemptive force and any implicit effect of FIFRA's registration and labeling scheme. The Court's discussion plainly rejected Monsanto's core argument that EPA's approval of Roundup's label preempts state common-law failure-to-warn claims like Hardeman's. As Dow and the United States did in *Bates*, Monsanto (and the United States once again as *amicus*) "greatly overstate the degree of uniformity and centralization that characterizes FIFRA. In fact, the statute authorizes a

[3] *See also* 544 U.S. at 450 ("Overenforcement of FIFRA's misbranding prohibition creates a risk of imposing unnecessary financial burdens on manufacturers; under-enforcement creates not only financial risks for consumers, but risks that affect their safety and the environment as well.").

relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450.

In *Bates*, as here, the plaintiff had brought various state common-law claims—including negligent failure to warn, *see* 544 U.S. at 442 n.15, 447–49—based on the inadequacy of the manufacturer's label. The Court interpreted FIFRA's "in addition to or different from" language to mean that "a state-law labeling requirement is not preempted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. As the district court noted in this case, "Hardeman's complaint explicitly bases his California-law failure-to-warn claims on Monsanto's alleged violation of FIFRA." Order Denying Motion to Dismiss and Motion to Stay at 2 (citing Complaint at ¶¶ 161–62). Monsanto thus cannot argue that California law imposes any greater or otherwise different labeling obligation on manufacturers as a matter of substantive principle. Instead, its argument is simply that once EPA has determined that Roundup's label is adequate, that decision binds the states such that any state common-law obligation to alter the label would necessarily be "in addition to or different from" federal requirements. Monsanto Br. at 29. That argument is flatly inconsistent with *Bates*.

Monsanto seeks to distinguish *Bates* on the ground that it involved a claim about a pesticide's efficacy or damage to crops, and EPA had waived review of these matters when it registers pesticides. *See* Monsanto Br. at 30; *Bates*, 544 U.S. at 440.

But nothing in the *Bates* opinion suggested that this fact was crucial. The test that the Court articulated was simply whether a state law claim was "equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. And in any event, Monsanto's argument ultimately turns on the claim that "EPA *has* frequently examined glyphosate's effects on human health and has determined that no cancer warning is appropriate." Monsanto Br. at 32. Preemption depends, even in Monsanto's view, on EPA's subsequent actions—not on the initial approval of Roundup's label. We address EPA's subsequent actions in the next Part.

C. FIFRA's Authorization of State Regulation in § 136v(a) Necessarily Restricts the Scope of Preemption.

A second fatal flaw in Monsanto's preemption arguments is that they fail altogether to take account of § 136v(a), which authorizes states to "regulate the sale or use of any federally registered pesticide or device in the State." *Bates* construed this language as permitting states to "ban or restrict the uses of pesticides that EPA has approved." 544 U.S. at 450. This is not an all-or-nothing choice. California may either "ban" *or* "restrict" the use of glyphosate if it so chooses. Restricting use without adequate warnings is an extremely common regulatory response to health risks, and there is no reason to believe that FIFRA prohibits California from taking that course.

Section 136v(a) confirms *Bates*'s suggestion that § 136v(b)'s "uniformity" requirement for labeling goes largely to form.[4] Otherwise, § 136v(b) would disable permitted state regulation from using any aspect of labeling as a regulatory tool. Monsanto's efforts to distinguish *Bates* actually concede the crucial point. Monsanto points out that *Bates* "concerned an efficacy warning, not a safety warning, and the Court emphasized that EPA had since 1978 waived manufacturers' obligation to confirm claims about their pesticides' efficacy . . . . Therefore, unlike Monsanto here, the manufacturer in *Bates* could have changed efficacy claims on its labeling without prior approval of the agency." Monsanto Br. at 37 n.12. But as Monsanto notes, the only textual exception allowing non-EPA-approved label changes is for "minor modifications," which Monsanto reasonably supposes would *not* have covered the modifications sought by the *Bates* plaintiffs. Monsanto Br. at

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[4] *See* 544 U.S. at 452 n. 26:

> The legislative history of the 1972 amendments suggests that Congress had conflicting state labeling regulations in mind when crafting § 136v(b). As one industry representative testified, "Some States might want the word 'flammable,' some 'inflammable.' . . . Some States might want red lettering; others orange, another yellow, and so forth. We ask this committee, therefore, to recognize, as the Congress has in a number of similar regulatory statutes, the industry's need for uniformity by providing for this in the act." Hearings on Federal Pesticide Control Act of 1971 before the House Committee on Agriculture, 92d Cong., 1st Sess., 281–283 (1971) (statement of Robert L. Ackerly). By contrast, the lengthy legislative history is barren of any indication that Congress meant to abrogate most of the common-law duties long owed by pesticide manufacturers.

37 n.11. Monsanto's argument thus necessarily reads the restriction on unilateral modification of a label as applying only to matters that federal authorities actively regulate under FIFRA—*not* to matters, like pesticide efficacy, that federal authorities have chosen *not* to police.

If that is true, then the same option to modify the label would apply to warnings about glyphosate's cancer risk. Section 136v(a) plainly allows California to *ban* glyphosate-containing products based on cancer concerns or to restrict their use. The fact that EPA has chosen *not* to require cancer warnings on such products is immaterial. Section 136v(a) allows California to regulate glyphosate as it sees fit *regardless* of the position that EPA takes on its risks to health. Nothing in the statute purports to give EPA authority to override a state's decision to exercise its authority under § 136v(a).

In addition to restricting the scope of express preemption,[5] § 136v(a) necessarily bars any implied or impossibility preemption that Monsanto might wish to derive from EPA's approval of Roundup's label. California law bars Monsanto from marketing glyphosate, or glyphosate-containing products, without a warning

[5] Justice Breyer wrote separately in *Bates* to emphasize EPA's authority to preempt state requirements by exercising its delegated authority to act with the force of law. *See* 544 U.S. at 454–55. But he did not address the extent to which such authority could be exercised consistent with § 136v(a), and his vote was not necessary to compose a majority in *Bates*.

of its carcinogenic risk. Even if FIFRA does bar Monsanto from giving that warning, the result would simply be that Monsanto may not market its product in California. Monsanto correctly notes that under many other federal preemption regimes, that would create an "impossibility" situation, *see* Monsanto Br. at 39 (citing *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013)), but that is because most federal regulatory regimes requiring premarket approval of medical drugs, devices, and the like are understood as conferring a federal right to market the product if that approval is granted.[6] As *Bates* recognized, FIFRA simply cannot be understood in this way. Instead, § 136v(b) grants California the right to ban glyphosate-containing products altogether if it disagrees with EPA about their risks. *See Bates*, 544 U.S. at 450.

II. Even If FIFRA Is Read More Restrictively, EPA's Actions in This Case Do Not Preempt Hardeman's Claims.

If the foregoing argument is correct, then it doesn't matter whether EPA would approve a cancer warning on Roundup or other glyphosate-containing products. California would *still* be entitled to forbid the sale of glyphosate-containing products without a cancer warning under § 136v(a). But even if EPA's preemptive authority is interpreted more broadly, that authority has not been validly

[6] *Bartlett*, for example, involved the regulatory regime for generic prescription drugs. That regime does not authorize states to ban such drugs from the market once the FDA has approved them.

exercised here.[7] Agency action has preemptive effect only when an agency acts with the force of law, and none of EPA's actions upon which Monsanto relies meets that standard.

A. Preemption Must Always Be Grounded in Congress's Authority, Not the Agency's.

The Supreme Court has repeatedly said that "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks Int'l Ass'n v. Schermerhorn*, 375 U.S. 96, 103 (1963)). To be sure, agency action can, in appropriate cases, preempt state law. But that effect is cabined in at least three ways. First, "[t]he Supremacy Clause . . . requires that pre-emptive effect be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures." *Wyeth*, 555 U.S. at 586 (Thomas, J., concurring in the judgment).[8] Second, only

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[7] As Hardeman argues, the parties disagree as to whether EPA has, in fact, made *any* relevant determination concerning Roundup's cancer risk (as opposed to glyphosate in general). Hardeman Br. at 42-43. *Amici* take no position on that question; our analysis assumes *arguendo* that EPA has made statements suggesting that it would reject a cancer warning for Roundup. We consider, instead, whether those statements carry any preemptive force.

[8] *See also* Stuart M. Benjamin & Ernest A. Young, *Tennis with the Net Down: Administrative Federalism without Congress*, 57 DUKE L.J. 2111, 2133–35 (2008) (insisting that the status of agency action as supreme federal law derives from Congress's action).

agency action "with the force of law" can preempt state law. *See Wyeth*, 555 U.S. at 576, 580. And third, this Court owes no special deference to an agency's conclusion that state law is preempted. *See id.* at 576–77. These principles derive not only from the Supremacy Clause but also from structural concerns. Unlike Congress, which represents state interests, federal agencies have incentives to expand their authority vis-à-vis the States, and their processes incorporate no protections whatsoever for state regulatory autonomy.[9]

The Supreme Court recently reaffirmed these principles in *Merck*, 139 S. Ct. 1668. *Merck* played out the implications of *Wyeth*, 555 U.S. 555, which had held that the federal regime governing name-brand prescription drugs did not preempt state common-law failure-to-warn claims because manufacturers were permitted to change their labels with FDA approval. The Court said there that "absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Wyeth*, 555 U.S. at 571. In *Merck*, the manufacturer asserted that it had such evidence based on the FDA's rejection of Merck's previous proposed

[9] *See generally* Ernest A. Young, *Executive Preemption*, 102 NW. U. L. REV. 869, 871-81 (2008); Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737, 783 (2004) (noting agencies' reluctance to consider the impact of their actions on state autonomy even when required to do so by standing executive orders).

change to its label and further communications between the agency and the manufacturer. *See* 139 S. Ct. at 1675. The court of appeals treated the question of whether the FDA would have approved the change sought by plaintiffs under state law as one of fact, ultimately to be determined by the jury at trial. *See id.* at 1675–76. The Supreme Court rejected that approach, however, concluding that the question was one of law. The central question, the Court said, is "whether federal law (including appropriate FDA actions) prohibited the drug manufacturer from adding any and all warnings to the drug label that would satisfy state law." *Id.* at 1678.

Justice Breyer's opinion in *Merck* made clear that not every agency indication of its views or preferences has preemptive effect.[10] Rather, "the only agency actions that can determine the answer to the pre-emption question, of course, are agency actions taken pursuant to the FDA's congressionally delegated authority. The Supremacy Clause grants 'supreme' status only to 'the *Laws* of the United States.'" *Id.* at 1679 (quoting U.S. CONST., art. VI, cl. 2). The Court gave several examples of agency action that might meet this standard:

> Federal law permits the FDA to communicate its disapproval of a warning by means of notice-and-comment rulemaking setting forth

[10] *See also Bates*, 544 U.S. at 455 (Breyer, J., concurring) (noting that agency action may have preemptive force when an agency acts "within appropriate legal and administrative constraints").

> labeling standards, see, *e.g.*, 21 U.S.C. § 355(d); 21 C.F.R. §§ 201.57, 314.105; by formally rejecting a warning label that would have been adequate under state law, see, *e.g.*, 21 C.F.R. §§ 314.110(a), 314.125(b)(6); or with other agency action carrying the force of law, cf., *e.g.*, 21 U.S.C. § 355(o)(4)(A).

Id. Although the Court left the ultimate resolution of Merck's preemption defense to the court of appeals on remand, the FDA's actions upon which Merck relied plainly would not meet the Court's standard. As Justice Thomas explained, absent a "statute, regulation, or other agency action with the force of law that would have prohibited [a manufacturer] from complying with its alleged state-law duties, its pre-emption defense should fail as a matter of law." *Id.* at 1683-84 (Thomas, J., concurring).

B. EPA Has Taken No Action with the Force of Law That Preempts Hardeman's Claims.

In this case, Monsanto can point to no legally binding action by EPA that forecloses Monsanto from complying with California law. Monsanto relies on various agency statements, studies, and a letter indicating EPA's view that glyphosate does not cause cancer and that applications to add a cancer warning to a glyphosate-containing product label would not be approved. *See* Monsanto Br. at 8–10. But as the district court rightly concluded, none of these acts possessed *the force of law* required for preemption. As Justice Thomas observed in *Merck*, "neither agency musings nor hypothetical future rejections constitute preemptive 'Laws' under the Supremacy Clause." 139 S. Ct. at 1682 (Thomas, J., concurring).

Monsanto concedes that EPA's actions can have preemptive force only when it acts with the force of law, *see* Monsanto Br. at 35, but its interpretation of what that means is at odds with all relevant authority. Monsanto suggests that EPA's actions here qualify because EPA "specifically invoked the authority delegated to it by FIFRA to determine what does and does not qualify as misbranding under the statute." Monsanto Br. at 35–36. But the Supreme Court has made clear that although federal law authorizes agencies to legally and legitimately take a wide variety of actions, including actions interpreting the federal requirements they enforce, only some of these delegations convey authority to act with the force of law. *See United States v. Mead Corp.*, 533 U.S. 218, 228–31 (2001) (indicating that courts afford *Chevron* deference only when agencies act with the force of law, and that not all actions agencies take are legislatively authorized to have this character).[11] *Mead* explained that "[i]t is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should

[11] *See also* Thomas R. Merrill, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467, 470 (2002) ("*Mead* makes clear that agencies act with the force of law only if Congress intended to delegate authority to them to so act.").

underlie a pronouncement of such force." *Id.* at 230.[12] Although Congress has empowered EPA to act in that way in some contexts, the agency did not exercise any such authority here.

Monsanto principally relies on an August 7, 2019 letter from Michael Goodis of EPA's Office of Pesticide Programs. That letter, sent in reaction to California's listing of glyphosate as a substance believed to cause cancer, stated the Office's view that California's action was incorrect, defended EPA's position as consistent both with other studies (referring to a 2017 "issue paper") and the conclusions of authorities in other countries, and announced that EPA "considers [California's] warning language based on the chemical glyphosate to constitute a false and misleading statement" under FIFRA. *See* Letter from Michael L. Goodis, EPA, Office of Pesticide Programs (Aug. 7, 2019), https://tinyurl.com/y552m94m. The letter certainly states EPA's viewpoint, but it does not constitute an exercise of the agency's delegated authority to act with the force of law. *See, e.g.*, *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 245–46 (3rd Cir. 2008) (refusing to accord preemptive force to a letter from the Commissioner of the FDA expressing the view

[12] *See also Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) ("[W]e determine whether an agency spoke with [the 'force of law'] under the standard set forth in [*Mead*] and its progeny.").

that California's requirement of a Proposition 65 warning for mercury amounted to "misbranding" under federal law).[13]

It is instructive to compare the August 7, 2019 letter with *Merck*'s examples of agency action with the preemptive force of federal law. The first was "notice-and-comment rulemaking setting forth labeling standards." *Merck*, 139 S. Ct. at 1679.[14] Second, Justice Breyer indicated that "formally rejecting a warning label that would have been adequate under state law" would be sufficient, citing the FDA's "complete response letter" procedure for rejecting proposed labeling changes, 21 C.F.R. § 314.110(a), and its procedure for refusing a new drug application in the first place, 21 C.F.R. § 314.125(b)(6). *See Merck*, 139 S. Ct. at 1679. Both of those procedures involve action on a specific party's application, are

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[13] *See also Kansas v. Garcia*, 140 S. Ct. 791, 807 (2020) "[T]he possibility that federal enforcement priorities might be upset is not enough to provide a basis for preemption. The Supremacy Clause gives priority to "the Laws of the United States," not the criminal law enforcement priorities or preferences of federal officers. Art. VI, cl. 2."); *see also Arizona v. United States*, 567 U.S. 387, 445 (2012) (Alito, J., concurring in part and dissenting in part) (describing as "remarkable" the government's claim that "a state law may be pre-empted, not because it conflicts with a federal statute or regulation, but because it is inconsistent with a federal agency's current enforcement priorities . . . [which] are not law"); David S. Rubenstein, *Administrative Federalism as Separation of Powers*, 72 WASH. & LEE L. REV. 171 (2015) (explaining how preemption by nonbinding agency action would undermine principles of federalism and separation of powers).

[14] *See also Mead*, 533 U.S. at 230-31 (noting notice-and-comment rulemaking as a paradigm case of agency action with the force of law).

highly formal, and include important procedural safeguards such as written notice and the opportunity for a hearing. Finally, Justice Breyer cited as an example of "other agency action carrying the force of law" the FDA's procedure for labeling changes requested by the Secretary, 21 U.S.C. § 355(o)(4)(A). *See Merck*, 139 S. Ct. 1679. That procedure is also quite formal, with action directed to a specific manufacturer, written notice to that manufacturer and an opportunity to respond, and a dispute-resolution procedure.

The August 7, 2019 letter, by contrast, was just a letter. Approximately one page in length, it summarized EPA's scientific and legal conclusions without much detail, and it was sent to all registrants whose products contain glyphosate. The broadside nature of the letter, which did not discuss specific pesticides, was significant given Hardeman's claim that Monsanto's Roundup is considerably more dangerous than ordinary glyphosate. Hardeman Br. at 15. In any event, the letter was not issued after a hearing and entailed no dispute resolution procedure of any kind. It was, in short, an indication of what EPA might decide should formal proceedings be initiated—but it was not the result of such proceedings.

If anything, EPA's statement was considerably less formal or developed than the agency actions that *lacked* the force of law in *Merck*. Despite its emphatic language, the August 7 letter was—procedurally speaking—"of a merely tentative or interlocutory nature," rather than "the consummation of the agency's

decisionmaking process." *Bennett v. Spear*, 520 U.S. 154, 156, 178 (1997).[15] But "communications suggesting that the [agency] would have denied a future labeling change" have no preemptive effect: "hypothetical agency action is not 'Law.'" *Merck*, 139 S. Ct. at 1683 (Thomas, J., concurring).

III. Monsanto's Broad Preemption Arguments Threaten Important Constitutional Values.

Monsanto's arguments for preemption in this case are extremely broad. It claims that FIFRA's regulatory scheme for pesticides, traditionally interpreted to "preserve[] a broad role for state regulation," *Bates*, 544 U.S. at 450, instead divests the states of nearly all authority. It asserts that preemption can occur, not only by the clear intent of Congress expressed in a statute, but by virtue of a one-page letter from a federal agency official. Given the breadth of these arguments, it is worth putting them in broader constitutional context.

The scope of federal preemption of state law is the central question in contemporary American federalism doctrine.[16] The Supreme Court's enumerated

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[15] *Cf. Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944–45 (D.C. Cir. 2012) ("[L]ike other agency advice letters that we have reviewed over the years, FDA warning letters do not represent final agency action subject to judicial review.").

[16] *See generally* Ernest A. Young, *Federal Preemption and State Autonomy*, in FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 249 (Richard Epstein & Michael Greve eds., 2007).

powers jurisprudence has generally given wide scope to Congress's regulatory authority, *see, e.g.*, *United States v. Comstock*, 130 S. Ct. 1949 (2010); *Gonzales v. Raich*, 545 U.S. 1 (2005), with the result that that authority is now, with certain important but relatively narrow exceptions, concurrent with that of the States. Given this broad scope of potential federal regulatory authority, the scope of federal preemption is the most critical piece of the Court's federalism doctrine in terms of preserving meaningful state autonomy. As Garrick Pursley has observed, "preemption may be the most important issue for modern federalism theory because it reallocates regulatory authority between the national and state governments." Garrick B. Pursley, *Preemption in Congress*, 71 OHIO ST. L.J. 511, 513 (2010).

By eliminating state regulatory authority so far as preemption extends, preemption undermines core values of federalism—that is, States' ability to respond to geographically divergent conditions and voter preferences, to experiment with innovative policies, and to compete with other jurisdictions to offer the most attractive mix of policies. *See generally Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991); *Wyeth*, 555 U.S. at 583–84 (Thomas, J., concurring in the judgment). As Professor Pursley explains, "[p]reemption . . . shapes the regulatory environment for most major industries—drugs and medical devices, tobacco, banking, air transportation, securities, cars, and boats[,] to name a few," and it "determines the diversity, scope, and delivery of a wide variety of important government services to

citizens"; as a result, "it is the issue of constitutional law that most directly impacts everyday life." Pursley, *supra*, at 513–14.[17]

Two primary structural constraints check the scope of federal preemption. First, the Supreme Court has long suggested that the principal institutional safeguard for state autonomy in our system derives from the States' representation in the national political process. *See Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528 (1985). The importance of that representation undergirds the oft-stated rule that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic*, 518 U.S. at 485. It also supports *Rice*'s presumption, because "a presumption against preemption promotes legislative deliberation" about the impact of proposed federal statute on state law. Robert R. M. Verchick & Nina Mendelson, *Preemption and Theories of Federalism*, in PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION (William W. Buzbee ed., 2009). As Justice O'Connor wrote for the Court, "'to give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'" *Gregory*, 501 U.S. at 464 (quoting Laurence H. Tribe, *American Constitutional Law*

[17] *See also* Young, *Ordinary Diet of the Law*, 2011 SUP. CT. REV. at 265–69; Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 805-07 (1994).

§ 6-25 (2d ed. 1988)). *Bates* reaffirmed the applicability and importance of that presumption in FIFRA cases like this one. *See* 544 U.S. at 431.

Our constitutional structure augments these "political safeguards" of federalism with *procedural* safeguards as well. "The lawmaking procedures prescribed by the Constitution safeguard federalism in an important respect simply by requiring the participation and assent of multiple actors . . . . In short, the imposition of cumbersome federal lawmaking procedures suggests that the Constitution 'reserves substantive lawmaking power to the states and the people both by limiting the powers assigned to the federal government and by rendering that government frequently incapable of exercising them.'" Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1339–40 (2001) (citations omitted). But "[t]he political and procedural safeguards of federalism are . . . readily circumvented through executive action." Young, *Executive Preemption*, *supra*, at 828. As Justice Stevens rightly observed, "[u]nlike Congress, administrative agencies are clearly not designed to represent the interests of States, yet with relative ease they can promulgate comprehensive and detailed regulations that have broad pre-emption ramifications for state law." *Geier v. American Honda Motor Co.*, 529 U.S. 861, 908 (2000) (Stevens, J., dissenting). It is thus crucial not to accord broad and independent preemptive powers to federal

agencies, especially where Congress has not clearly intended to delegate them authority to act with the force of law.

These general propositions do not, of course, decide particular cases. But they do highlight "the practical importance of preserving local independence, at retail, i.e., by applying pre-emption analysis with care, statute by statute, line by line, in order to determine how best to reconcile a federal statute's language and purpose with federalism's need to preserve state autonomy." *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 160 (2001) (Breyer, J., dissenting). They also underscore the importance of arguments set out earlier in this brief: that Congress's efforts to preserve state regulatory autonomy and *Rice*'s presumption against preemption—in FIFRA, as elsewhere—should be scrupulously enforced; that impossibility preemption should be narrowly construed; and that agencies should not be afforded preemptive powers outside narrow limits.

CONCLUSION

The district court's rulings rejecting Monsanto's preemption arguments should be affirmed.

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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

CERTIFICATE OF COMPLIANCE FOR BRIEFS

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

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I, Ashley Keller, hereby certify that on March 23, 2020, I caused a copy of the foregoing Brief for *Amici Curiae* Public Law Scholars in Support of Plaintiff-Appellee to be served upon all counsel by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

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