No. 17-290

IN THE
Supreme Court of the United States

MERCK SHARP & DOHME CORP.,
Petitioner,

v.

DORIS ALBRECHT, ET AL.,
Respondents.

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

BRIEF OF PUBLIC LAW SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

[Public Law Scholars listed on inside cover]

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QUESTION PRESENTED

Whether the Food and Drug Administration's initial rejection of Petitioner's request to add certain warnings to the label of its name-brand drug preempted state tort claims by legally barring Petitioner from adding to its label the warnings required by state law?

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INTEREST OF AMICI CURIAE

Amici are public law scholars whose teaching and scholarship has addressed federal preemption of state law.[1] Mindful of the gap that sometimes exists between the academy and the concerns of the bench and bar, we seek to bring our scholarship to bear on the particular preemption questions at issue in this case.

Our scholarly interest in preemption arises from teaching and writing in a variety of related fields, including constitutional law, administrative 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 Lyons is an Associate Professor 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. Nina Mendelson is the Joseph L. Sax Collegiate Professor

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represent that they authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than *amici* or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. At an earlier stage, Lieff Cabraser represented plaintiffs in two cases in the Fosamax MDL, which were administratively terminated pending this Court's decision on Defendants' Petition for Certiorari. These plaintiffs were not subject to the summary judgment order on appeal to this Court and Lieff Cabraser no longer represents them. Pursuant to Rule 37.3(a), counsel for *amici* also represent that all parties have consented to the filing of this brief.

the University of Michigan Law School. 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.

SUMMARY OF ARGUMENT

This case presents basic questions about the extent to which federal administrative agencies will determine the preemptive impact of federal law on state regulation. The parties and the court of appeals focused on the preemptive intent of the Food and Drug Administration (FDA), which rejected a "prior approval supplement" (PAS) application by Merck to make certain changes to its warning label for the drug Fosamax. They have also focused on the likelihood that the FDA eventually would have rejected a different label change, which Respondents argue state tort law required, had Merck chosen to implement that change through the FDA's "changes being effected" (CBE) procedure. *Amici* submit that both sets of arguments inappropriately reorient the preemption inquiry from *Congress*'s preemptive intent to that of the agency.

This Court's precedents establish two critical points: First, Congress intended broadly to preserve state law, including state tort remedies for failure to warn, as a complement to the Food, Drug, and Cosmetic Act's (FDCA) regulation of warning labels for name-brand drugs. *See Wyeth v. Levine*, 555 U.S. 555, 566-68, 574-75 (2009). *Wyeth* held that state tort remedies were consistent with the FDCA's purposes and objectives, and that it is ordinarily possible to comply both with the Act's labeling regime and state tort duties. *See id.* at 570-73, 574-76. Second, this

Court has made clear that the key question for impossibility preemption—the only sort of preemption argued here—is whether it was "lawful under federal law for the Manufacturers to do what state law required of them." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). The FDA's "complete response letter" denying Merck's initial PAS application is thus relevant *only* to the extent that it would legally foreclose Merck from changing its label through the CBE process.

This brief argues that the PAS denial letter has no such legal effect and thus cannot preempt Respondents' state law claims. Neither Petitioner nor the United States points to any authority indicating that the PAS process, once initiated, forecloses a manufacturer from utilizing the CBE option. The FDA's "complete response letter" cannot itself preempt state claims because it was not final agency action and did not carry the force of law. And in any event the PAS application involved a proposed warning different from the one Respondents allege state law requires.

Nor should the FDA's letter ruling be considered to be "clear evidence that the FDA would not have approved a change to [Fossamax's] label." *Wyeth*, 555 U.S. at 571. *Wyeth* indicated that such a showing would require an actual attempt to change the label under the CBE procedure that the FDA then rejected. *See id.* at 572. Speculation about how the FDA *might* have responded to an application for a different label that Merck never made contravenes *PLIVA*'s insistence that the preemption inquiry not "take into account hypothetical federal action." 564 U.S. at 621 n.6. Moreover, shifting the focus away

from Congress's intent to what the agency *might* have done invites troublesome probabilistic inquiries that raise difficult procedural complications, such as whether preemption must go to the jury or whether plaintiffs should be allowed discovery concerning the FDA's decisionmaking process. And such an inquiry inappropriately puts the agency, not Congress, in charge of preemption.

Any uncertainties regarding Congress's preemptive intent in this case must be resolved in light of this Court's longstanding presumption against preemption. *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Petitioner's *amici* have used this case to launch a general assault on the *Rice* presumption, and to argue that that presumption is inapplicable in implied conflict preemption cases like this one. This Court has rejected these arguments before, and it should reject them again because *Rice*'s presumption plays an integral role in preserving the autonomy of the states.

ARGUMENT

I. Congress Preserved a Key Role for State Tort Law as Part of its Statutory Scheme for Regulating Name-Brand Drugs.

Petitioner's preemption argument in this case faces an uphill climb. The problem is not simply that this Court applies a general presumption against preemption. *See Rice*, 331 U.S. at 230. Rather, the primary obstacle to Petitioner's argument is that this Court has already interpreted Congress's scheme for regulating the warning labels of name-brand drugs in light of the *Rice* presumption against preemption.

In *Wyeth*, this Court broadly considered the FDCA's labeling regimes for such drugs; it concluded that Congress "took care to preserve state law," 555 U.S. at 567, and that state tort remedies "provided appropriate relief for injured consumers," *id.* at 574. And the Court rejected *both* an impossibility preemption argument and an argument that state-law failure to warn claims conflicted with the "purposes and objectives" of the FDCA. *See id.* at 570-73, 574-76. Those holdings leave only the very narrowest of pathways for a preemption argument in this case—if in fact they leave any pathway at all.

Wyeth's reading of the FDCA carries the "enhanced force" of *stare decisis* that accrues "when a decision . . . interprets a statute." *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2409 (2015); *see also Patterson v. McClean Credit Union*, 491 U.S. 164, 172-73 (1989). This Court's cases make clear that some federal regulatory regimes, such as the National Bank Act, reflect Congress's intent to broadly preempt state law. *See, e.g.*, *Barnett Bank of Marion Cnty., N.A. v. Nelson*, 517 U.S. 25, 32-33 (1996). But Congress intended other federal regimes to preserve much state regulation, and this Court has accordingly tended not to find preemption in those areas. *See, e.g.*, *Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 205-08 (1983) (concluding that federal regime governing safety of nuclear power plants was intended to preserve traditional state authority over public utility regulation). *Wyeth* made clear that the FDCA's prescription drug regime falls into the latter category. That binding construction of the FDCA must inform this Court's resolution of the more specific issues presented in this case.

The FDCA's provisions for regulating name-brand drugs have displayed a conspicuous and consistent concern for preserving state common law claims as part of the regulatory scheme. Congress rejected a proposal to include a private right of action for damages in the 1938 FDCA because "a common law right of action exists." *Hr'g on S. 1944 Before a Subcomm. of the Comm. on Commerce of the U.S. Senate*, 73d Cong. 2d Sess. 400, 403 (1933). And in the 1962 amendments, which substantially expanded the FDA's powers under the Act, Congress included a savings clause: "Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962). This approach stands in marked contrast to Congress's regulation of medical devices, which includes an express preemption provision that "no State … may establish or continue in effect with respect to a device intended for human use any requirement - (1) which is different from, or in addition to, any requirement applicable under this chapter to the device; and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

Congress amended the FDCA again in 2007 with the Food & Drug Administration Amendments Act of 2007 (FDAAA), and it again chose not to enact a generally applicable express preemption provision, despite efforts by the pharmaceutical industry to ob-

tain such a provision.[2] The legislative record indicates that Congress considered the amendments' preemption implications[3] and that, ultimately, Congress decided to expressly preempt only a very narrow category of state regulation. *See* Pub. L. 110-85, Title VIII, § 282(d), 121 Stat. 922 (Sept. 27, 2007) (preempting state registering requirements for certain clinical trials).[4] And Congress rejected a provision in the Senate bill that would have required FDA approval of all label changes, instead "adopt[ing] a rule of construction to make it clear that manufacturers remain responsible for updating their labels." *Wyeth*, 555 U.S. at 568 (citing 121 Stat. 925-26); *see*

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[2] *See* Pub. L. No. 110-85, 121 Stat. 823 (2007); David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461, 468 & n.27 (2008) (noting the disappointment of counsel for the pharmaceutical industry).

[3] *See* 153 Cong. Rec. S11832, col. 3, S11833, cols. 1-2 (daily ed. Sept. 20, 2007) (Sen. Kennedy); *id*. at S11834, cols. 2-3 (Sen. Leahy); *id*. at S11835, col. 3 (Sen. Durbin).

[4] Petitioner's *amici* have argued that the 2007 FDAAA "modif[ies] the preemption equation presented in *Levine*." Br. of *Amici Curiae* Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization in Support of Petitioner in No. 17-290, *Merck Sharp & Dohme Corp. v. Albrecht* at 4 (Sept. 2018). This is an odd assertion, given that this Court's opinion in *Wyeth* explicitly considered the impact of the FDAAA. For the Court, the most salient aspect of the 2007 amendment was its rejection of a provision in the Senate bill to require FDA preapproval for all label changes. *See* 555 U.S. at 567-68. Neither this Court nor the United States, which briefed the impact of the FDAAA in *Wyeth*, suggested that the FDAAA broadened the FDCA's preemptive effect. *See* Br. for the United States as *Amicus Curiae* Supporting Petitioner in No. 06-1249, *Wyeth v. Levine*, at 32-33 (June 2008) (stressing only that "those amendments do not reflect any intent to *limit* the FDCA's preemptive effect") (emphasis added).

21 U.S.C. § 355(o)(4)(I). There would be little point to preserving the manufacturer's responsibility regardless of FDA action if the FDA had sole responsibility to determine the label's content. Rather, Congress plainly intended that other actors—in particular, courts adjudicating state tort claims—would also have a role in identifying inadequate warnings.

Nor has Congress granted the FDA authority to unilaterally alter the preemptive effect of its drug labeling regulation. The Medical Devices Act expressly preempts "different" or "addition[al]" state law requirements and delegates to the FDA a specific role in determining the Act's preemptive reach, but nothing in the FDCA indicates that Congress intended FDA drug labeling regulation to have equivalent effect. Nor is there any provision conferring authority on FDA to make a determination as to when consistent but different or additional state requirements would be preempted. *Compare* 21 U.S.C. § 360k, *with* 21 U.S.C. § 301, *et seq.*; *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495-496 (1996) (discussing the FDA's unique role in determining the scope of § 360k's pre-emptive effect).

This Court's decision in *Wyeth* noted all this statutory history when it held that Congress did not intend to broadly preempt state law claims against manufacturers of name-brand drugs. 555 U.S. at 573-81. Justice Stevens's majority opinion explained that "through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain ad-

equate as long as the drug is on the market." *Id.* at 570-71. This emphasis on the manufacturer's responsibility underscores that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. The Court noted that "[f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." 555 U.S. at 579. *Wyeth* thus concluded that Congress failed to provide any federal remedy for consumers under the FDCA precisely because "it determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* at 574.

Wyeth emphasized that "'[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" 555 U.S. at 575 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–167 (1989). This Court thus construed the text and history of the FDCA as fundamentally preservative of state law claims. As a statutory holding that Congress may revisit if it is so inclined, *Wyeth*'s reading of the FDCA is entitled to a *stare decisis* presumption of "enhanced force." *Kimble*, 135 S. Ct. at 2409. Whatever the impact of *Rice*'s broader presumption against preemption in this case, *Wyeth*'s settled reading of the FDCA imposes a heavy burden on Petitioner to establish preemption. And to the extent that Petitioner's arguments would tend to undermine the role for state law that Congress sought to preserve, those arguments should be rejected.

II. The Preemption Inquiry in this Case Should Focus on Whether Merck Could Legally Have Changed Its Label to Comply with State Law.

This Court has repeatedly said that "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." *Medtronic*, 518 U.S. at 485 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963). As just discussed, *Wyeth* held that Congress generally intended to preserve state tort law when it enacted the FDCA's regulatory regime for brand-name drugs. And this Court's decision in *PLIVA*, 564 U.S. at 618, makes clear that Congress intended state law to give way only where federal law makes it illegal for a drug manufacturer to unilaterally alter its label in order to comply with a state-law duty. The preemption question in this case thus reduces to whether Merck could have added a warning about atypical femoral fractures to its label without further action by the FDA.

However, the parties to this case (and the court of appeals) have focused on a subtly but importantly different question. Petitioners have drawn Respondents into a vigorous debate over the meaning of the FDA's "complete response letter" rejecting Merck's proposed change to the Fosamax label, and what that letter signifies about how the agency might have responded if Merck had proposed a label change focused—as Respondents argue state law required—on atypical femoral fractures. *Amici* suggest that this focus mistakes the nature of the preemption inquiry.

Because the purpose of Congress is the "ultimate touchstone" for preemption, the question is whether *Congress*—not the agency—intended to displace state law under the circumstances of this case. This could have happened in only three ways:

1) Congress could have intended to preempt any state-law based changes that departed from the FDA-approved label;

2) Congress could have delegated the authority to preempt particular state law duties to the FDA;

3) Congress could have delegated to the FDA the authority to take particular substantive actions with regard to a manufacturer's label that might create a conflict with a state-law duty to warn.

The first of these possibilities describes Congress's regime for *generic* drugs that this Court held to have preemptive effect in *PLIVA*, but *Wyeth* rejected arguments that the name-brand regime had similar effect. 555 U.S. at 568-71. The second describes the FDCA regime for medical devices, which *Wyeth* contrasted with the name-brand drug regime. *Id.* at 567. The third certainly *does* describe the name-brand drug regime, at least insofar as manufacturer that unilaterally changed its label through the CBE process in response to a state-law duty could not continue to use that label if the FDA rescinded it. *Id.* at 571.

There is no such FDA action here, however. This case concerns whether a quite different agency action—the denial of Merck's voluntary PAS application for pre-clearance of a particular label—also effectively preempts a state-law duty to warn. One

might argue for that result on two distinct grounds: first, that the denial *itself* made it illegal for Merck to adopt the warnings state law required; or second, that the denial indicated the FDA's intent to reject the state-law-required label in the future if Merck were to adopt it through the CBE process.

Amici submit that neither of these theories is viable. We think it is unlikely that Congress intended for PAS denials to foreclose resort to the CBE process, much less to be independently preemptive of state law. And it is even less likely that Congress would have wanted courts to speculate about the import of PAS denials for future decisions that the FDA might make. In assessing these arguments, moreover, this Court should be mindful that both theories would undermine Congress's concern for preserving the role of state law in drug safety regulation and shift key decisions about preemption to the FDA. As we discuss below, shifting preemptive authority to administrative agencies undermines key aspects of our federal structure.

A. This Court should avoid shifting the focus of the preemption inquiry from Congress's intent to that of the agency.

The opening line of the United States' brief states that "[t]his case concerns the circumstances under which a decision of the [FDA] rejecting proposed changes to the labeling of a brand-name drug preempts state-law tort claims that allege that the drug manufacturer failed to provide adequate warnings on its labeling." United States Brief at 1. This characterization suggests a shift in focus from Con-

gress's intent to the agency's action. 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).[5] Second, only agency action "with the force of law" can preempt state law. *See Wyeth*, 555 U.S. at 576, 580.[6] And third, this Court owes no special deference to an agency's conclusion that state law is preempted. These principles derive from structural concerns that federal agency processes—in contrast to Congress's lawmaking procedures—incorporate no protections whatsoever for state regulatory autonomy.[7]

Federal agencies do not represent the states, and their interests do not always align. *See,*

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[5] 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).

[6] *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 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, *The Paradox of Administrative Preemption*, 38 Harv. J. L. & Pub. Pol'y 267 (2015).

[7] *See generally* Ernest A. Young, *Executive Preemption*, 102 Nw. U. L. Rev. 869, 871-81 (2008).

e.g. Letter from Steven Rauschenberger, president, National Conf. of State Legis. to Michael Leavitt, secretary of HHS (Jan. 13, 2006) (complaining that the FDA's preemption preamble at issue in *Wyeth* showed a "complete disregard for our dual system of government"). Indeed, agencies are notoriously unwilling to consider federalism values even where standing executive orders require them to do so. *See* Nina A. Mendelson, *Chevron and Preemption*, 102 Mich. L. Rev. 737, 783 (2004) ("In 1999, the General Accounting Office reported that only five federalism impact statements had been prepared for the over 11,000 final rules agencies issued between April 1996 and December 1998."). Administrative action likewise evades not only the political but also the *procedural* safeguards of federalism. To the extent that Article I's lawmaking gauntlet tends to preserve state autonomy, federal agency action threatens federalism by circumventing that procedure. *See* Bradford R. Clark, *The Separation Powers as a Safeguard of Federalism*, 79 Tex. L. Rev. 1321, 1433 (2001); Young, *Executive Preemption*, *supra* note 7, at 876-77.

It is true, of course, that agency expertise will be valuable with respect to certain aspects of the preemption decision. But agencies have little comparative advantage with respect to the basic task of statutory construction. Preemption determinations require interpretations of both federal and state law, moreover, and federal agencies have no expertise with respect to the latter. *See* Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. Rev. 727, 758 (2008). Here, for example, the FDA has no particular expertise to assess what warnings state law might require. Deference to agency

preemption determinations, moreover, allows agencies to expand their own power through preemption. *See* Merrill, *Preemption*, *supra*, at 756; William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. Rev. 1574, 1590 (2007) (identifying agencies' incentive to make themselves the sole locus of regulatory choice).

This Court has been wary of according independent preemptive effect to agency actions and of deferring to an agency's determination of the preemptive effects of its regulations or governing statutes. In *Wyeth*, this Court emphasized that "Congress has not authorized the FDA to pre-empt state law directly," and it refused to defer to the FDA's opinion that state failure to warn claims were preempted. 555 U.S. at 576-81. Likewise, Justice Thomas's majority opinion in *PLIVA* rejected the suggestion that courts should "defer to an agency's ultimate conclusion about whether state law should be pre-empted." 564 U.S. at 613 n.3.

As discussed above, *Wyeth* held that Congress intended broadly to preserve state law governing drug warnings; hence, this Court restricted preemption to cases of impossibility and construed that category narrowly. *See* 555 U.S. at 570-73, 574-76. The key question in an impossibility case is whether it was "lawful under federal law for the Manufacturers to do what state law required of them." *PLIVA*, 564 U.S. at 618. As Professor Nelson puts it, "preemption occurs if and only if state law contradicts a valid rule established by federal law." Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 231 (2000). *PLIVA*—which involved failure to warn claims against generic

drugmakers that must replicate the brand-name version's warning label—thus stressed that "[i]f the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *PLIVA*, 564 U.S. at 618. In this case, the FDA's complete response letter does not establish impossibility under this standard.

B. The FDA's complete response letter did not render it illegal for Merck to comply with state law duties to strengthen its label.

Neither Petitioner nor the United States makes a serious argument that the FDA's denial of Merck's PAS application independently made it illegal for Merck to change its label unilaterally in order to satisfy its state-law duty to warn. Petitioner does assert that "[b]ecause of that rejection, it was impossible for Merck to revise its label to conform to the state-law duties that respondents allege, without violating federal law in the process." Petitioner's Brief at 35. But that assertion neither cites any statutory or regulatory provision nor articulates how the PAS and CBE procedures interact within the regulatory scheme. The structure of that scheme makes clear, however, that a PAS denial cannot itself have preemptive effect.

First, the PAS procedure is an alternative to the CBE procedure permitting a manufacturer to unilaterally change its label in response to safety concerns. Neither Petitioner nor its *amici* have pointed to any statutory or regulatory provision indicating that rejection of a PAS application would fore-

close resort to the CBE procedure.[8] Reading a PAS application to forestall resort to the CBE process, moreover, would run counter to the FDCA's general intent to preserve the role of state tort remedies.

Second, Merck never pursued the PAS process to a final conclusion. A complete response letter "informs sponsors of changes that must be made before an application can be approved, with no implication as to the ultimate approvability of the application." 73 Fed. Reg. 39,588 (2008). An applicant receiving such a letter has three options: (1) "[r]esubmit the application . . . , addressing all deficiencies identified in the complete response letter"; (2) [w]ithdraw the application"; or (3) request a hearing at which FDA will make a final determination whether to approve or reject the application. 32 C.F.R. § 314.110(b). The agency's communication to Merck thus plainly contemplated further action of various kinds. It was "of a merely tentative or interlocutory nature," rather than "the consummation of the agency's decisionmak-

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[8] Construing a PAS rejection to operate in this way would be inconsistent with statute's handling of a similar situation, in which the Secretary of Health and Human Services may request changes to a label based on new safety information. *See* 21 U.S.C. § 355(o)(4). Such a request by the Secretary initiates an iterative process that may ultimately result in a coercive order. Critically, however, this section has a "[r]ule of construction" that this Court has construed to underscore the ultimate responsibility of the manufacturer for the adequacy of the label. *See* § 355(o)(4)(I); *Wyeth*, 555 U.S. at 567-68. This rule strongly suggests that the manufacturer remains subject to state tort duties notwithstanding the Secretary's initiation of a process to change the label.

ing process." *Bennett v. Spear*, 520 U.S. 154, 156, 178 (1997).[9]

Because it is not final and therefore not subject to judicial review, and because it has a relatively low degree of formality, the FDA's complete response letter is not agency action with the force of law. The agency's letter thus cannot preempt state law on its own. Nor can it render manufacturer action impossible. Even if a final agency order resolving the PAS process might have preemptive effect, Merck never took the process that far. Until the agency takes action with the force of law foreclosing the label changes that state law requires, there can be no impossibility preemption.

Finally, the FDA rejected Merck's PAS application for a label change that was quite different from the one that Respondents allege state law requires. It makes no sense to assume that because the FDA did not approve a particular change that would have added warnings to Fosamax's label, the agency would have rejected *any* change to that label warning—even one warning of a distinct risk. *See* Michael M. Gallagher, *Clear Evidence of Impossibility Preemption after* Wyeth v. Levine, 51 Gonzaga L. Rev. 439, 466-67 (2016) ("If the FDA neither considered nor rejected the precise warning sought by the plaintiff, then the failure to warn claim is not preempted."). Even if the PAS denial were final

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[9] *Cf. Holistic Candlers and 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.").

agency action with the force of law, that action answered a question that Respondents have not asked.

C. The complete response letter cannot establish preemption by providing evidence of what the FDA *would have done* had Merck changed its label to meet state law requirements.

Petitioner's primary argument seems to be not that the complete response letter preempted state law in itself but rather that it signaled what would have happened if Merck had tried to adopt a label warning of atypical femoral fractures unilaterally through the CBE procedure. This argument likewise cannot establish preemption.

The first problem with this way of framing the question is that it contravenes *PLIVA*. That decision firmly resisted the notion that probabilistic judgments about what the FDA *might* have done should govern the preemption analysis. In that case, the plaintiffs argued that although federal law forbade a generic drug manufacturer from unilaterally changing its label, the manufacturer could have notified FDA of the danger and sought changes both for the brand-name and the generic label. But the possibility that FDA might ultimately have mandated such a change was insufficient to avoid preemption. *See PLIVA*, 564 U.S. at 619-21. *PLIVA* thus rejected the notion that "conflict pre-emption must take into account hypothetical federal action." *Id.* at 621. "The question for 'impossibility'," this Court insisted, "is whether the private party could *independently* do

under federal law what state law requires of it." *Id.* at 620 (emphasis added).

The second set of difficulties are practical. Much of the debate between the parties and their other *amici* concerns whether the complete response letter's preemptive effect raises a question of law, to be decided by the court, or a question of fact that must go to the jury. If the preemption question is a probabilistic one about what the FDA might do, based not only on complete response letters but also any other available evidence of the agency's intent, then the Third Circuit's conclusion that this is a jury question makes some sense. But surely that is a reason to change the question—not simply to take it from the jury. Preemption is ordinarily a legal question for the court precisely because it focuses on conventional interpretation of congressional intent, not on an effort to assess the future intentions of agency officials.

Treating Petitioner's probabilistic counterfactual as determinative would have other adverse consequences. If validity of preemption defenses in drug cases comes to turn on what the FDA would do in various circumstances that it has not already ruled upon, then parties to state tort litigation will have strong incentives to seek discovery from the FDA concerning its internal deliberations. It should not create incentives to burden the agency with inquiries into the agency's decisionmaking process in an effort to divine how the agency might respond to a question not put to it.

To be sure, *Wyeth* suggested that clear evidence that the FDA would not have approved a

change to [a drug's] label" could establish impossibility. 555 U.S. at 571. But the Court telegraphed what such a showing would require in the very next paragraph, stating that "Wyeth . . . does not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA." *Id.* at 572. This strongly suggests that a manufacturer must adopt the warning required by state law pursuant to the CBE procedure and then have the FDA actually reject that order through final action with the force of law. This is the only standard consistent with *PLIVA*'s insistence that the preemption inquiry may not "take into account hypothetical federal action." 564 U.S. at 621.

This Court should hesitate before extending *Wyeth*'s proviso any further. The suggestion that a drug manufacturer need not adopt a state-required warning because the FDA would likely reject it is similar in structure to futility-based exceptions to rules requiring litigants to pursue certain remedies or limiting the grounds upon which a court can act. When such exceptions are allowed, they tend to be very narrow. A party cannot challenge a state or local government's taking of property, for example, until the government has definitively rejected the proposed property use, and it must pursue available procedures to obtain such a ruling unless such an action would be futile. *See, e.g.*, *Palazzollo v. Rhode Island*, 533 U.S. 606, 624-26 (2001). But the relevant state governmental entity must have taken a definitive position that leaves no doubt as to the incursion on the plaintiff's property rights. *See id.*[10] Similarly,

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[10] *See also MacDonald, Sommer & Frates v. Yolo Cty.*, 477 U.S. 340, 348 (1986) ("[A]n essential prerequisite to [a regulato-

a reviewing court may generally uphold administrative agency action only on the grounds upon which the agency relied. *SEC v. Chenery Corp.*, 318 U.S. 80 (1943). A court may avoid a remand only if "[t]here is not the slightest uncertainty as to the outcome of a proceeding before the [agency]," and thus "[i]t would be meaningless to remand." *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6 (1969).[11]

In the context of collateral review of state criminal convictions by federal *habeas corpus*, by contrast, there generally is *no* such futility exception. Rather, failure to present an argument to the state courts is a procedural default barring federal *habeas* review, even if state precedent suggests the argument would likely be rejected. *See, e.g.*, *Engel v. Isaac*, 456 U.S. 107, 130 (1982). The reason is that "[e]ven a state court that has previously rejected a constitutional argument may decide, upon reflection, that the contention is valid." *Id.*

These examples suggest that *Wyeth*'s dictum should be construed to absolve drug manufacturers from seeking to modify their labels as required by state law only in very narrow circumstances—if at all. As in the takings cases, manufacturers should have to show that the agency has taken final and definitive action concerning the required warnings (and not some other warning that might or might not be

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ry takings claim] is a final and authoritative determination of the type and intensity of development legally permitted on the subject property.").

[11] *See also INS v. Orlando Ventura*, 572 U.S. 12, 17 (2002) (recognizing an exception to the remand requirement only in very rare circumstances).

similar). But there is also much to be said for affording the FDA—like the state courts in the *habeas* context—an opportunity to reconsider by provisionally adopting the state-required label through the CBE process even if a PAS denial were directly on point.

III. The Presumption Against Preemption Applies in this Case.

For over seventy years, this Court has begun its preemption inquiries "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230. Petitioner's *amici* seek to use this case as a vehicle for a general assault on the *Rice* presumption and its application in implied preemption cases—both arguments that this Court has rejected before.[12] For the reasons we explore below, this Court should reject them again.

A. The *Rice* presumption is well-established and consistent with the text of the Supremacy Clause.

Although it may not be necessary to decide this case, given *Wyeth*'s interpretation of this particular statutory regime, the *Rice* presumption against preemption remains 'cornerstone[] of [this Court's] pre-emption jurisprudence." *Wyeth*, 555 U.S. at 565 (citing *Medtronic*, 518 U.S. at 485). That is true not-

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[12] *See generally* Ernest A. Young, *'The Ordinary Diet of the Law': The Presumption Against Preemption in the Roberts Court*, 2011 Sup. Ct. Rev. 253, 276-78 (2012) (discussing the Court's rejection of prior attacks on the presumption against preemption).

withstanding the assertion of Petitioner's *amici* that "[n]o basis exists in the Constitution for applying a presumption against preemption—in this or any other case." Brief of Washington Legal Foundation as *Amicus Curiae* in Support of Petitioner in No. 17-290, *Merck Sharp & Dohme Corp. v. Albrecht*, at 18 (Sept. 20, 2018). Pro-preemption *amici* have been making that argument for decades, and this Court has never adopted it.

The reason for that is that the presumption against preemption plays a central role in modern federalism jurisprudence. *See generally* Young, *supra* note 12, at 257-83 . This Court's Commerce Clause cases leave most areas of regulatory concern subject to concurrent national and state authority, with the result that the most critical federalism questions concern not so much what Congress can do, as a matter constitutional power, but what it has done—and how much room it has left for state regulation. *Compare, e.g.*, *Gonzales v. Raich*, 545 U.S. 1 (2005) (construing Congress's commerce power broadly to reach homegrown medical marijuana), *with Gonzales v. Oregon*, 546 U.S. 243 (2006) (construing the Controlled Substances Act not to authorize the Attorney General to preempt Oregon's Death with Dignity Act). Historically speaking, the *Rice* presumption against preemption developed as a response to the expansion of Congress's commerce power during the New Deal period: as the scope of Congress's action expanded, it was essential to ensure that federal activity did not disable large swaths of state regulation without clear evidence that Congress intended to do so. *See* Stephen A.

Gardbaum, *The Nature of Preemption,* 79 Cornell L. Rev. 767, 806-07 (1994).[13]

Moreover, the *Rice* presumption fits well with this Court's recognition that structural and political safeguards play a critical role in protecting state autonomy against federal encroachments. *See Garcia v. San Antonio Metro. Trans. Auth.*, 469 U.S. 528, 550-54 (1985). In *Gregory v. Ashcroft*, 501 U.S. 452 (1992), this Court explained:

> [I]nasmuch as this Court in *Garcia* has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise. "[T]o 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."

Id. at 464 (quoting Laurence Tribe, *American Constitutional Law*, § 6-25, at 480 (2d ed. 1988)); *see also*

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[13] Petitioner's *amici* are simply incorrect to claim that the *Rice* presumption does not "enjoy a long pedigree." Washington Legal Foundation Br., *supra*, at 20. The doctrine arose in the 1930s and 1940s, at the same time that this Court accepted a considerably broader notion of Congress's regulatory powers. *See Rice*, 331 U.S. at 229-36; *Mintz v. Baldwin*, 289 U.S. 346, 350-52 (1933) (both articulating a presumption against preemption); *Wickard v. Filburn*, 317 U.S. 111 (1942); *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937) (both adopting a more expansive view of Congress's regulatory authority). *See generally* Gardbaum, *supra*, at 805-07.

Murphy v. NCAA, 138 S. Ct. 1461, 1477 (2018) (emphasizing the importance of political checks on federal action). Requiring clear evidence of Congress's intent to alter the federal balance—whether by regulating the qualifications of state officers, as in *Gregory*, or by displacing state law through preemption—is important in two respects. It provides a political check, by providing notice to the States' representatives in Congress, and a procedural check, by requiring that state-displacing choices overcome the Constitution's built-in hurdles to federal legislative action.[14]

As *Gregory* illustrates, the *Rice* presumption is one of many rules of construction that protect state autonomy. *See, e.g.*, *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (requiring that Congress clearly state conditions on grants of federal funds to the States); *Jones v. U.S.*, 529 U.S. 848, 858 (2000) (requiring a clear statement of Congress's intent to regulate at the outer limits of its Commerce Clause authority); *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989) (requiring a clear statement of Congress's intent to subject states to liability under federal statutes).[15] Because preemption questions arise so frequently, however, the *Rice* presumption is the most important of these rules.

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[14] *See generally* Young, *Ordinary Diet*, *supra* note 12, at 265; Clark, *supra*, 1330.

[15] *See generally United States v. Bond*, 572 U.S. 844, 857-58 (2014) (stressing the importance of these rules, including the *Rice* presumption); Thomas W. Merrill, *Rescuing Federalism After* Raich: *The Case for Clear Statement Rules*, 9 Lewis & Clark L. Rev. 823 (2005).

Petitioner's *amici* contend that a presumption against preemption is contrary to the original understanding of the Supremacy Clause, *see* Washington Legal Foundation Br., *supra*, at 18-19 (citing Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 304 (2000). Other *amici* made the same argument in *Wyeth*,[16] and we discussed it at some length in our *amicus* brief in that case.[17] The short answer is that Professor Nelson's originalist argument objects only to an anti-preemption rule of construction considerably stronger than anything this Court has applied under *Rice*. *See* Nelson, *supra*, at 293-94 (stating that "[o]ne should not take [his] point too far" and that he has no objection to the notion that "judges should generally be reluctant to infer pre-emption."); Young, *Ordinary Diet*, *supra* note 12, at 311-15 (elaborating this point). In any event, this Court has necessarily rejected any argument that *Rice* is unconstitutional by continuing to apply the presumption.

B. *Rice*'s presumption against preemption applies in implied conflict cases.

Petitioner's *amici* also make a narrower argument that, even if *Rice* is good law, it should not apply in *implied* preemption cases. The *amici* supporting the petitioner in *Wyeth* made this precise argu-

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[16] *See* Br. of the Chamber of Commerce of the United States of America as *Amicus Curiae* in Support of Petitioner in No. 06-1249, *Wyeth v. Levine*, at 18 (June 2008).

[17] *See* Br. of *Amicus Curiae* Constitutional and Administrative Law Scholars in Support of Respondent in No. 06-1249, *Wyeth v. Levine*, at 9-14; *see also* Young, *Ordinary Diet*, *supra*, at 310-24 (discussing Professor Nelson's argument).

ment in that case,[18] but this Court explicitly rejected it, observing that "this Court has long held to the contrary." 555 U.S. at 565 n.3 (citing *California v. ARC America Corp.*, 490 U.S. 93, 101-102 (1989); *Hillsborough Cty. v. Automated Medical Labs., Inc.*, 471 U.S. 707, 716 (1985); and *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002)).[19] The cases that Petitioners' amici cite as "openly question[ing] whether the presumption should ever apply in conflict-preemption cases," Washington Legal Foundation Br., *supra*, at 21, say no such thing. Rather, those cases—*Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000), and *United States v. Locke*, 529 U.S. 89, 108 (2000)—both involved foreign affairs considerations raising questions whether the ordinary *Rice* presumption should apply in that context.[20]

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[18] *See* Chamber of Commerce Br. in *Wyeth*, *supra*, at 27 ("[T]he Court should take this opportunity to make clear that the presumption against preemption – whatever its applicability to questions of field preemption – is simply inapplicable to cases involving conflict preemption.").

[19] *See also, e.g.*, *Pharm. Research and Mfrs. of America v. Walsh*, 538 U.S. 644, 666 (2003) (plurality opinion) (applying the *Rice* presumption to a conflict claim under the Medicaid statute); *accord id.* at 681 n.4, 682 (Thomas, J., concurring in the judgment) (same); *Bldg. & Constr. Trades Council v. Associated Builders & Contractors of Mass./R. of the Metropolitan Dist. I., Inc.*, 507 U.S. 218, 224 (1993) (applying *Rice* presumption to conflict preemption under the NLRA); *Ca. Bed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 281, 288 (1987)) (applying a presumption against preemption in the course of rejecting a claim that a state pregnancy discrimination statute conflicted with Title VII).

[20] *See also* Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 Sup. Ct. Rev. 175 (2001) (considering whether

Whatever the merits of the position that *Rice* should not apply (or should apply differently) in *express* preemption cases, we think the case for a presumption against preemption is particularly strong where Congress has not articulated its preemptive intent in statutory text.[21] And the same analysis of

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different presumptions should govern preemption in foreign and domestic cases). Petitioner's *amici* also stress that, of five preemption cases during the 2011, "*none* discussed the presumption against preemption." Washington Legal Foundation Br. at 24. Although no majority opinion invoked *Rice* explicitly that term, *Whiting* stated that "[o]ur precedents 'establish that a high threshold must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act.'" *Chamber of Commerce v. Whiting*, 563 U.S. 582, 607 (2011) (quoting *Gade v. National Solid Wastes Mgt. Assn.*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring in part and in the judgment)). And taken altogether, the 2011 term cases "provide some evidence that the Court is raising the overall bar for conflict preemption"—not lowering it. Young, *Ordinary Diet*, *supra* note 12, at 328.

[21] One of Petitioner's *amici* asserts that "[t]his Court has recently abolished any 'presumption against preemption' in express-preemption cases." Washington Legal Foundation Br., *supra*, at 21 (quoting *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016)). But that oversimplifies the situation dramatically. *Franklin* did state that "because the statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." 136 S. Ct. at 1946 (quoting *Whiting*, 563 U.S. at 594). But the presumption against preemption *never* applies when statutory language is clear. That is probably why *Franklin* did not discuss—and certainly did not overrule—decisions like *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008), which stated that "when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'" *Id.* at 77 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). As *Bates* explained, concluding that a

the Supremacy Clause's original understanding that Petitioner's *amici* rely upon to challenge the *Rice* presumption generally also concludes that *conflict* preemption should be construed far more narrowly than under current law.[22] And although conflict preemption cases lack an express preemptive text to which to apply a rule of statutory construction, they typically do involve two kinds of ambiguity: First, the substantive content of federal law may be ambiguous, so that it is unclear whether that law actually creates a conflict with state law. In such cases, the presumption suggests courts should interpret federal

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statute expressly preempts some aspects of state law "says nothing about the *scope* of that pre-emption." 544 U.S. at 443-44 (emphasis in original).

Franklin's statement on express preemption clauses quoted *Whiting*, 563 U.S. at 594, and cited *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 946 (2016). But neither case purported to revisit *Altria* or *Bates*, and neither supports categorically excluding *Rice*'s presumption where there is an express preemption clause. *Whiting*, like *Franklin*, found the language of the federal statute clear and had no occasion to resort to canons of construction. The Court may also have wished to avoid deciding whether *Rice* applies to laws governing immigration—an area of exceptionally broad federal authority. *Gobeille* held simply that the presumption against preemption was overcome by state law's "direct regulation of a fundamental ERISA function," while acknowledging that *Rice* does control in many instances under ERISA. 136 S. Ct. at 946 (citing *De Buono v. NYS-ILA Medical and Clinical Services Fund*, 520 U.S. 806 (1997) (applying *Rice* in an ERISA case notwithstanding ERISA's express preemption clause)).

[22] *See* Nelson, *supra*, at 260 (arguing that state law should be preempted only if there is a "logical contradiction" between state and federal law); *see also Wyeth*, 555 U.S. at 590 (Thomas, J., concurring in the judgment) (adopting this part of Professor Nelson's analysis and concluding that it requires a narrower approach to conflict preemption).

law narrowly to avoid the conflict.[23] Second, a given conflict between federal and state law may be sufficiently minor that Congress would have preferred for state and federal law to operate side by side.[24] Here, the *Rice* presumption suggests simply that minor conflicts should be insufficient to displace to state law.[25] In either sort of case, the presumption provides a useful default rule that protects state regulatory autonomy without foreclosing federal action where Congress's intent is clear.

Petitioners' *amici* are right about this much: This Court has been inconsistent in its references to

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[23] *Cf. Bates*, 544 U.S. at 449 (stating, in an express preemption case, that in choosing between "plausible alternative reading[s]" of a federal statute, courts "have a duty to accept the reading that disfavors pre-emption").

[24] *See, e.g.*, *Crosby*, 530 U.S. at 373 (observing that "[w]hat is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects"); *Bonito Boats*, 489 U.S. at 167 (acknowledging that sometimes Congress intends "to tolerate whatever tension there [is] between" state and federal law).

[25] *See, e.g.*, Young, *Ordinary Diet*, *supra* note 12, at 274-76; Thomas W. Merrill, *Preemption*, *supra*, at 743 (observing that preemption cases assess not simply whether "federal law . . . is in tension with state law" but also "whether this tension is sufficiently severe to warrant the displacement of state law"). Even leading advocates of broad preemption acknowledge this point. *See* Alan Untereiner, *The Defense of Preemption: A View from the Trenches*, 84 Tulane L. Rev. 1257, 1260 (2010) (observing that in conflict preemption cases, "courts make judgments about whether the degree of tension between federal and state laws rises to the level of an impermissible conflict under the Supremacy Clause"). And Professor Nelson argues that Congress is unlikely to intend to preempt all state law conflicting in any way with a federal statutes, without regard to degree. *See* Nelson, *supra*, at 279-82.

the presumption against preemption.[26] That phenomenon should not surprise anyone, however. *Rice* has never been an overwhelming presumption, and thus preemption cases turn importantly on the text, structure, and purposes of specific federal statutes. In many cases, a majority of the Court may find that statute *clearly* preempts (or does not preempt) state law. Because canons of construction come into play only when statutes are ambiguous, there is no reasons to invoke or discuss *Rice* in such cases. It follows that failures to mention the presumption in particular cases are not necessarily evidence of desuetude. And of course this Court *does* continue to invoke the presumption.[27]

CONCLUSION

The holding of the United States Court of Appeals for the Third Circuit that Respondents' state-law failure to warn claims are not preempted should be affirmed.

Respectfully submitted,

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[26] *See* Young, *Ordinary Diet*, *supra* note 12, at 308-09 (discussing possible reasons for this).

[27] *See, e.g.*, *CTS Corp. v. Waldburger*, 134 S. Ct. 2175, 2188 (2014) (plurality opinion); *Bond*, 572 U.S. at 858.

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