No. 17-290

In the Supreme Court of the United States

MERCK SHARP & DOHME CORP., PETITIONER,

v.

DORIS ALBRECHT, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF AMICI CURIAE OF VIRGINIA, CALIFORNIA, CONNECTICUT, DISTRICT OF COLUMBIA, ILLINOIS, INDIANA, IOWA, KENTUCKY, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, MONTANA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, AND WASHINGTON IN SUPPORT OF RESPONDENTS

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INTEREST OF THE AMICI CURIAE

"[B]oth the Federal Government and the States wield sovereign powers." *Murphy* v. *National Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1475 (2018). Valid federal statutes are, of course, "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. But preemption analysis "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth* v. *Levine*, 555 U.S. 555, 565 (2009) (quotation marks and citation omitted). States also have a strong interest in preserving state laws that protect their citizens from unsafe drugs and providing remedies to consumers injured by drugs. The amici States thus have a substantial interest in the Court's resolution of this case.

SUMMARY OF ARGUMENT

Unlike other federal statutes regulating medical devices, vaccines, and over-the-counter drugs, the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, contains no provision expressly preempting state tort claims. In *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the defendant company "abandoned" any field preemption argument, *id.* at 560, and this Court concluded that state tort claims do not categorically "stand as an obstacle to the accomplishment of Congress' purposes in the FDCA." *Id.* at 581.

That leaves one remaining form of preemption: impossibility. In *Wyeth*, this Court considered and rejected an impossibility-preemption argument under the same statute at issue here because the party urging preemption had "failed to demonstrate that it was impossible for it to comply with both federal and state requirements." 555 U.S. at 573. The Court acknowledged that the result may have been different had the company presented "clear evidence that the FDA would not have approved a change to [the drug's] label." *Id.* at 571. But the Court perceived no such evidence in the record before it, *id.* at 572, and it emphasized that "[i]mpossibility pre-emption is a demanding defense," *id.* at 573.

In this case, petitioner seeks to convert the Court's careful qualifier into a sweeping exception that threatens to destroy the underlying rule. In *Wyeth*, the Court squarely rejected the company's possibility-of-impossibility defense, concluding that it was not enough to suggest that FDA *might* have rejected a proposed warning when neither the alternative warning nor the information that would have supported it had been presented to the agency. See *Wyeth*, 555 U.S. at 572. Yet here, petitioner urges preemption of claims arising out of its failure to disclose *one* type of risk (atypical femoral fractures) based on a previously submitted warning to the FDA about a *different* type of risk (stress fractures). See U.S. Br. 8 n.7 (distinguishing between the more common stress or "fatigue" fractures and insufficiency fractures).

Petitioner's argument is inconsistent with this Court's reasoning in *Wyeth* and would upset Congress' careful balance between federal and state regulatory authority in this important area of traditional state concern. See *Wyeth*, 555 U.S. at 578 (noting that "FDA traditionally regarded state law as a complementary form of drug regulation"). Petitioner's proposed rule disregards the cornerstone of this Court's preemption jurisprudence (the presumption against preemption) and replaces it with a presumption of preemption in any situation where the FDA previously declined a request for a label change. Adopting such a rule would unduly circumscribe the state remedies available to injured consumers and shift the costs of injuries from those whose products inflict them to the States and communities where injured people live and work. It also would limit the efficacy of state law rules designed to ensure that companies internalize the costs of their business decisions, including the decision to withhold safety information from the public.

For these reasons, the amici States urge this Court to affirm the decision below

ARGUMENT

"Impossibility pre-emption is" and should remain "a demanding defense." *Wyeth* v. *Levine*, 555 U.S. 555, 573 (2009). It is "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Id.* at 570–71 (emphasis added). "[T]he very idea that FDA would bring an enforcement action against a manufacturer for

strengthening a warning . . . is difficult to accept." *Id.* at 570 (emphasis added); see *id.* (emphasizing that "neither Wyeth nor the United States has identified a case in which the FDA has done so"). And this Court has emphasized that state tort actions play a critical role in "uncover[ing] unknown drug hazards" by "motivat[ing] injured persons to come forward with information." *Id.* at 579.

All of those considerations counsel against preemption here. Drug manufacturers have managed to comply with both federal drug labeling obligations and state common law for almost 80 years. Far from presenting the kind of irreconcilable obligations that justify a categorical rule of preemption, the availability of common law tort suits complements and completes the federal scheme. See *Wyeth*, 555 U.S. at 578 (emphasizing that "[t]he FDA has limited resources to monitor the [then] 11,000 drugs on the market"). Although petitioner proposed a warning about one type of risk (stress fractures), it did not propose a warning sufficient to inform consumers about the risk that forms the basis of respondents' state law tort claims (atypical femoral fractures). Accordingly, the court of appeals correctly rejected petitioner's impossibility-preemption defense.

I. Fundamental federalism principles counsel against petitioner's broad view of impossibility preemption

The Constitution expressly reserves to the States or the people all powers not delegated to the federal

government. See U.S. Const. amend. X. "The States [thus] retain substantial sovereign authority under our constitutional system," and "[t]his federalist structure of joint sovereigns preserves to the people numerous advantages." *Gregory* v. *Ashcroft*, 501 U.S. 452, 457–58 (1991). As especially relevant here, "a decentralized government . . . will be more sensitive to the diverse needs of a heterogeneous society"; "allows for more innovation and experimentation in government"; and "makes government more responsive by putting the States in competition for a mobile citizenry." *Id.* at 458.

All of those interests go unserved when state laws are preempted. This concern may have had less salience in the early years of our Republic when federal law was "generally interstitial in its nature." Henry M. Hart, Jr. & Herbert Wechsler, *The Federal Courts and the Federal System* 470 (2d ed. 1973). But today's Congress asserts vast authority over many areas of everyday life, see, *e.g.*, *Gonzales* v. *Raich*, 545 U.S. 1, 17 (2005), and the opportunities to preempt state law have correspondingly broadened.

As a result, the Court has adopted a variety of interpretive rules that protect state authority. For example, the Court requires a "plain statement" before it will conclude that Congress meant to "upset the unusual constitutional balance of federal and state powers." *Gregory*, 501 U.S. at 460–61. The Court will not read a federal statute as abrogating a State's immunity from suit unless Congress makes such an "intention unmistakably clear in the language of the statute."

Atascadero State Hosp. v. *Scanlon*, 473 U.S. 234, 242 (1985). And, as relevant here, any preemption analysis "start[s] 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* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

There is nothing atextual about this method of interpretation. To the contrary, these rules—including the presumption against preemption—serve a crucial structural function. They help to safeguard the Founders' overarching constitutional design—a design crafted to give States a significant role in day-to-day governance. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996) ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.").

These structural benefits redound to Congress and the States alike. The presumption against preemption rests on the assumption that Congress—not a court—has the power to dictate the bounds of congressional purpose. See *Gade* v. *National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part, concurring in judgment) (emphasizing that "it is Congress rather than the courts that preempts state law"). And without this safeguard, States themselves will often lack political recourse. Both practical realities and this Court's precedent mean that "the political process" provides the primary "protection of the States against intrusive exercises of

Congress' Commerce Clause power." *Gregory*, 501 U.S. at 464. But States (and their citizens) cannot use the political process to protect against overly broad preemption of state tort law if courts accept the invitation to craft broad rules of preemption that are untethered to the text of any congressional act.

This case illustrates the point. "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history." *Wyeth*, 555 U.S. at 574. But adopting a sweeping form of obstacle or impossibility preemption here would presume that Congress, although silent on the issue, would have wanted state law displaced. Such an approach conflicts with basic canons of statutory construction and the judiciary's institutional role. It also would undermine the protections the political process is designed to afford the States—especially where, as here, the argument for preemption is based not on the text of any congressional enactment but rather on the everyday actions of a federal agency. See *Hines* v. *Davidowitz*, 312 U.S. 52, 75 (1941) (Stone, J., dissenting) (emphasizing that "it is difficult to overstate the importance of safeguarding against . . . diminution of state power by vague inferences as to what Congress might have intended if it had considered the matter or by reference to our own conceptions of a policy which Congress has not expressed").

II. Regulation of consumer safety is an area of traditional state concern

"[I]n all pre-emption cases," this Court "start[s] 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." *Wyeth*, 555 U.S. at 565 (internal quotation marks and citations omitted). This is "particularly" so where "Congress has legislated in a field which the States have traditionally occupied." *Id.*

States have long regulated in the area of drug labeling. The duty to warn patients and physicians about emerging safety risks predates—by decades—the advent of federal regulation of drugs. See, *e.g.*, *Thomas* v. *Winchester*, 6 N.Y. 397 (1852); see also *Lohr*, 518 U.S. at 485 (noting the "primacy of state regulation of matters of health and safety"). When the FDA first emerged on this scene, it too understood its mandate to be wholly consistent with this longstanding state duty. See, *e.g.*, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979) (FDA labeling decisions do not "influence civil tort liability of the manufacturer"); 59 Fed. Reg. 3,944, 3,948 (Jan. 27, 1994) (recognizing that "product liability plays an important role in consumer protection," in notice proposing rules to protect the identities of individuals reporting adverse drug reactions); 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (observing that FDA labeling "regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements," in FDA's final guidance on prescription drug labeling).

Against this backdrop of deeply rooted state tort law, Congress chose not to include preemptive language in the FDCA. Nor did it include such language in the years to follow, though "[j]udgments against manufacturers of various FDA approved products were by no means rare." Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims after* Medtronic, 64. Tenn. L. Rev. 691, 704 (1997). Although Congress did opt to preempt state law requirements for medical devices and vaccines,[1] it left state requirements relating to pharmaceutical labeling untouched.

In 1962, Congress enlarged the FDA's powers and shifted the burden of proof from the FDA (to prove the drug would cause harm) to the manufacturer (to prove the drug was safe). Here too, Congress could have added a provision preempting state law. But, instead, Congress "took care to *preserve* state law" with a new "saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Wyeth*, 555 U.S. at 567 (citing FDCA § 202).

As this Court has explained "[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

[1] In contrast to the FDCA, which contains no express preemption provision, Congress chose to expressly preempt state actions based on injuries arising from medical devices, 21 U.S.C. § 360k(a), and vaccines, 42 U.S.C. §§ 300aa-22(b)(1) and (e); along with state positive-law requirements with respect to over-the-counter drugs, 21 U.S.C. § 379r(a).

to stand by both concepts and to tolerate whatever tension there is between them." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989) (internal quotation omitted). Here, the long history of state tort litigation against manufacturers of prescription drugs—and Congress's repeated failure to amend the FDCA in response—"adds force to" the conclusion that Congress did not intend to preempt such litigation in the ordinary case. *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

III. Petitioner's proposed rule would disturb the balance between state and federal regulation that this Court struck in *Wyeth*

1. Petitioner proffers the following rule: "If a manufacturer proposes to warn about a risk, discloses what it knows about that risk, and gets rebuffed by the FDA, failure-to-warn claims against it are preempted as a matter of law." Pet. Br. 20. But respondents dispute that the warning petitioner presented to the FDA (stress fractures) encompassed the harm underlying respondents' state tort law claims (atypical femoral fractures). What is more, petitioner has not demonstrated that the label change it proposed to the FDA would have satisfied its state law duty to warn. Any construction of the test that would allow petitioner to prevail without such a showing would slight the presumption against preemption and the critical role of state tort law in this area.

Petitioner's sweeping approach to impossibility preemption also raises a host of other problems. For

one thing, it would create perverse incentives on the front end. Under petitioner's theory of preemption, the FDA's rejection of a proposed warning based on inadequate evidence would bar later tort claims—even if the inadequate evidence was itself the result of the company's own lack of diligence. Such an approach would reward manufacturers who fell short in their efforts to collect information about a particular risk and create incentives to learn as little as possible before proposing label changes to the FDA. It would also undercut state law warning requirements whose application is predicated on constructive (rather than actual) knowledge.[2] And it would create an immunity from state tort liability based on something that only the manufacturer can ultimately control: "what [*the manufacturer*] knows" about a given risk. Pet. Br. 20. That cannot be what Congress intended.

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[2] See, *e.g.*, *Nicholson* v. *American Safety Utility Corp.*, 476 S.E.2d 672 (N.C. App. 1996) (interpreting N.C. Gen. Stat. Ann. § 99B-5 to require seller to warn of any hazard associated with use of product if seller has actual or constructive knowledge of particular threatening characteristic of product); *Frey* v. *Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977) (stating that "where the manufacturer or the seller of a product has actual *or constructive* knowledge of danger to users, the seller or manufacturer has a duty to give warning of such dangers") (emphasis added); La. Stat. Ann. § 9:2800.57 ("[A] product is unreasonably dangerous because an adequate warning about the product has not been provided if . . . the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic"); Miss. Code Ann. § 11-1-63(c) (adopting actual or constructive knowledge standard for product liability under failure-to-warn theory).

Petitioner's proposed rule also would remove any incentive to continue gathering information after the FDA has declined to approve a label change. As the Federal Government seems to acknowledge, see U.S. Br. 27–28, a manufacturer might discover new evidence about a risk after the FDA has already rejected a label change regarding that risk. Depending on the nature of the new information, the FDA's earlier rejection may no longer signal the agency's ongoing opposition to future label changes. Nevertheless, here too, petitioner's proposed rule would assume impossibility because the company has made a single, unsuccessful attempt to amend the drug's label—even when new risk information has changed the underlying calculus.[3]

Both of these problems present opportunities for gamesmanship. For example, a company seeking to avoid state tort liability could propose a label change that it knows the FDA will reject based on then-insufficient evidence. Though designed for failure, that proposal would head off any potential future claims based on the company's failure to warn should evidence of that risk later accumulate. Even worse, a company could propose a change framed in terms that it knows the FDA will reject with the goal of preempting any subsequent state law claims that it can stuff under the same general umbrella. This Court should be wary of a rule that would permit a regulated entity to

[3] For example, more than 200 plaintiffs involved in this litigation were injured after the FDA's rejection of petitioner's label change. Even if relevant, the FDA's decision in May of 2009 may not necessarily indicate its position 16 months later when some plaintiffs incurred injuries. J.A. 26–27, 40.

manufacture impossibility preemption by strategically submitting overbroad or inaccurate warnings.

Finally, petitioner's application of its proposed rule vividly illustrates the rule's ambiguities and its potential for mischief. It is straightforward enough to determine whether the FDA rejected a specific proposed warning. Petitioner's proposal, however, sweeps much broader and would result in preemption whenever a manufacturer "proposes to warn about *a risk*." Pet. Br. 20 (emphasis added). But that formulation skates over a host of difficult questions about how (and how broadly) courts are to define the word "risk" in this context. In particular, it tells us nothing about what "risk" the company aimed to disclose and thus which warnings the FDA refused to permit.

These details matter. The parties to this case actively dispute whether petitioner's proposed label change would have warned respondents about the risks that ultimately resulted in their injuries.

Just as important, the parties also dispute whether the label that petitioner proposed would have satisfied the state law duty to warn. If the proposed label would have satisfied the state law duty in this case, the FDA's rejection might constitute some evidence that petitioner could not have complied with both its state and federal obligations.[4] But if the proposed changes would not have satisfied the state law

[4] That said, even a square FDA rejection of *one* formulation that would have satisfied the duty to warn imposed by state law would not necessarily mean that FDA would have rejected *any* formulation that satisfied the state law duty.

duty to warn, the FDA's rejection of *those* changes would have little bearing on the preemption question at hand. See *Wyeth*, 555 U.S. at 571 (framing the issue as whether FDA "would not have approved" the type of change that plaintiffs argue state law required). A party should not be able to claim impossibility preemption by showing that federal regulators rejected a warning that would not have satisfied the state law duty that that party stands accused of violating. Absent a showing that the federal regulators did (or obviously would have) rejected a warning that satisfied state law, a manufacturer cannot show that compliance with both state and federal law is actually impossible.

The Court's decision in *Wyeth* resolves this case, and because the manufacturer can comply with both state and federal law, there is no preemption here. If the Court is inclined to clarify the rationale behind its preemption decisions in this area, the amici States urge the Court to account for at least three features that petitioner's proposed rule does not. *First*, the comprehensiveness of the evidence presented to the FDA. *Second*, whether any additional evidence of the risk came to light after the FDA's decision. And *third*, whether the company's proposed label would have satisfied the state law duty to warn in the first instance. If the company has not presented the full scope of available evidence to the agency; if material evidence post-dating the FDA's decision exists; or if the proposed label change would not have satisfied the

relevant state duty, the defendant should not be able to avail itself of impossibility preemption.

2. A theory of "impossibility" preemption that is unmoored from actual impossibility is nothing more than obstacle preemption masquerading as impossibility preemption. Any such approach cannot be reconciled with the history of drug regulation or basic principles of statutory construction, separation of powers, and federalism. It likewise cannot be reconciled with this Court's conclusion in *Wyeth* that "common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA." 555 U.S. at 581.[5]

Obstacle preemption requires courts to go beyond the text of a statute to determine the broader intent (or intents) behind the enactment. But Congress knows how to express its intent: in the text of the laws it drafts and enacts. Where, as here, it fails to express an intent to preempt state law, this Court should be wary of implying that intent in a vacuum.

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[5] See also Brief of Amici Curiae Vermont, Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, West Virginia, Virginia, Washington, Wisconsin, and Wyoming in Support of Respondent, *Wyeth* v. *Levine*, 555 U.S. 555 (2009) (discussing the problems associated with implied obstacle preemption).

Implied obstacle preemption of this kind mires courts in policy-laden quests for overarching, unstated legislative purposes. See *Williamson* v. *Mazda Motor of Am., Inc.*, 562 U.S. 323, 340 (2011) (Thomas, J., concurring in the judgment) (describing "purposes-and-objectives pre-emption as inconsistent with the Constitution because it turns entirely on extratextual 'judicial suppositions' "). This task is made all the more difficult by the fact that Congress does not preempt any and all state laws that might somehow "frustrate" achievement of one of its objectives.

For example, even if *one* goal of Congress might be to "foster[] uniformity in . . . regulations," that objective may not be "unyielding." *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 70 (2002). A state tort action that frustrates the goal of uniformity might advance legislators' expectation that injured consumers have access to remedies. *Id.* at 64 (state tort actions, "unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims"). Congress also might conclude that state tort liability provides a necessary supplement to a regulatory regime.[6] Or an enacted law might simply reflect a compromise among legislators balancing the benefits of stricter federal standards

[6] See Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 310 (2007) (noting that state tort liability can "spur[ ] change in regulatory or corporate procedures, as well as extend[ ] knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators"); see also *Bates*, 544 U.S. at 451 ("tort suits can serve as a catalyst" to improve industry and federal regulatory practices).

against the dangers of displacing state tort actions. See *Landgraf* v. *USI Film Prods.*, 511 U.S. 244, 286 (1994) ("Statutes are seldom crafted to pursue a single goal, and compromises necessary to their enactment may require adopting means other than those that would most effectively pursue the main goal.").

Given the difficulty inherent in this task, many members of the Court have expressed concern with the potential scope of this brand of conflict preemption. See *Bates*, 544 U.S. at 459 (Thomas, J., joined by Scalia, J., concurring in the judgment in part and dissenting in part) (approving "th[e] Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"); *Geier* v. *American Honda Motor Co., Inc.*, 529 U.S. 861, 907 (2000) (Stevens, J., joined by Souter, Thomas, and Ginsburg, JJ., dissenting) (discussing the importance of "prevent[ing] federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes"); *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part, concurring in judgment) ("A free-wheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law.").

Here too, "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70–year history." *Wyeth*, 555 U.S. at 574.

* * *

Impossibility preemption is rare, but that is by design. In this context, it should, at minimum, require a company to show that a federal agency has prevented it (or obviously would have prevented it) from acting in compliance with the state law duty to warn. The States urge the Court against any broad expansion of the impossibility exception in *Wyeth*, lest it become the same sort of roving "obstacle" preemption that the Court initially rejected in that case.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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