No. 22-3412

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

IN RE: FOSAMAX (ALENDRONATE SODIUM)
PRODUCTS LIABILITY LITIGATION

On Appeal from the United States District Court
for the District of New Jersey

Case Nos. 3:08-cv-00008-FLW-LHG *et al.* / MDL 2243
Chief Judge Freda L. Wolfson

BRIEF OF THE COMMONWEALTH OF VIRGINIA AND 22 OTHER STATES AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS

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IDENTITY AND INTEREST OF *AMICI*

Amici curiae are the Commonwealth of Virginia, the State of Alaska, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Georgia, the State of Idaho, the State of Illinois, the State of Indiana, the Commonwealth of Kentucky, the State of Maryland, the Commonwealth of Massachusetts, the State of Minnesota, the State of Mississippi, the State of Montana, the State of Nebraska, the State of New Jersey, the State of New Mexico, the Commonwealth of Pennsylvania, the State of South Carolina, the State of Texas, the State of Utah, and the State of Vermont (collectively, the *Amici* States). *Amici* States submit this brief pursuant to Federal Rule of Appellate Procedure 29(a)(2) on behalf of Plaintiffs-Appellants.

Amici States raise an important interest in this case: protecting state sovereignty in the face of creeping federal preemption. "[B]oth the Federal Government and the States wield sovereign powers." *Murphy v. National Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1475 (2018). Yet when courts give unduly sweeping preemptive effect to federal law, thereby displacing state law unnecessarily, the courts undermine the state authority critical to maintaining our federalist balance. Although federal

law will occasionally preempt state law impliedly, the Supreme Court has stressed that such instances are rare. Courts encroach on state autonomy when they instead interpret implied federal preemption more broadly.

This litigation raises the question of the extent to which courts will allow States to regulate drugs that are used by their residents. Giving agency action the sort of sweeping preemptive effect that the district court gave it here threatens to shrink this important body of state consumer-protection law. The *Amici* States thus have a substantial interest in the Court's resolution of this case.

INTRODUCTION

The doctrine of preemption is a "precarious component of our system of federalism under which the states and federal government possess concurrent sovereignty, subject to the limitation that federal law is 'the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 687 (3d Cir. 2016) (quoting U.S. Const. art. VI, cl. 2). Our constitutional scheme is built upon a "compound republic," with power allocated between "two distinct governments." *Ibid.* Due respect for this system leads courts to apply "a strong presumption

against preemption in areas of the law that States have traditionally occupied." *Ibid.* (quoting The Federalist No. 51, at 323 (James Madison) (Clinton Rossiter ed., 1961)). Because preemption "upset[s] the usual constitutional balance of federal and state powers," federal law typically preempts state law only when Congress makes its intention to preempt state law "unmistakably clear in the language of the statute." *Gregory v. Ashcroft*, 501 U.S. 452, 460–61 (1991).

The federal law at issue here is the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* The FDCA contains no provision that expressly preempts state tort claims related to prescription drugs. And the Supreme Court has concluded that state tort claims do not "stand as an obstacle to the accomplishment of Congress' purposes in the FDCA." *Wyeth v. Levine*, 555 U.S. 555, 560, 581 (2009).

The only way that Defendant-Appellee can show preemption of Plaintiffs-Appellants' state tort claims is through "impossibility preemption," which occurs only when it is "impossible for a private party to comply with both state and federal requirements." *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 480 (2013). Impossibility preemption "is a demanding defense," *Wyeth*, 555 U.S. at 573, and the

"possibility of impossibility is not enough," *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019) (cleaned up). To show impossibility in a failure-to-warn case, a drug manufacturer must provide "clear evidence" that the manufacturer "fully informed" the U.S. Food and Drug Administration (FDA) "of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." *Ibid*.

Here, however, the district court held that claims of failure to warn of the risk of atypical femoral fractures were preempted because the FDA had rejected the manufacturer's proposal to use a label that identified a *different* risk than the one giving rise to this lawsuit. The district court's judgment expands the sweep of impossibility preemption well beyond the narrow boundaries that the Supreme Court has established and would upset Congress' careful balance between federal and state regulatory authority in this important area of traditional state concern. The ruling risks undermining core principles of federalism and could prevent States from allowing their citizens to hold pharmaceutical companies to account for their actions. It also could promote gamesmanship, including

incentivizing companies to file broad and inadequate label requests to the FDA in an effort to immunize themselves from future tort claims.

This Court should reverse.

SUMMARY OF THE ARGUMENT

"[A]ll preemption cases 'start 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.'" *Sikkelee*, 822 F.3d at 687 (quoting *Wyeth*, 555 U.S. at 565). The FDCA contains no express preemption provision for prescription drugs, "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth*, 555 U.S. at 575. And the Supreme Court has rejected obstacle preemption in the prescription drug context as "an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* at 573.

Defendant-Appellee contends that the doctrine of impossibility preemption applies here, but this Court should reject the district court's overbroad application of impossibility preemption. First, fundamental principles of federalism require a narrow view of impossibility preemption, but Defendant-Appellee's victory below risks a dramatic

expansion of the doctrine. Our Constitution permits States to exercise regulatory power to protect their citizens as long as they are not "prohibited" from doing so. U.S. Const. amend. X. Thus, "[i]mpossibility pre-emption is" and must remain "a demanding defense." *Wyeth*, 555 U.S. at 573. State sovereignty is a bedrock principle of our constitutional system, and one that produces "numerous advantages" for the country. *Gregory*, 501 U.S. at 458. Among these, a robust view of state sovereignty helps ensure a decentralized approach to lawmaking that is "more sensitive to the diverse needs of a heterogenous society," encourages "innovation . . . in government," and creates competition that makes the government more responsive. *Id.* at 457–58. This Court should protect that system here.

Second, the presumption against preemption does its most important work in areas that "States have traditionally occupied." *Wyeth*, 555 U.S. at 565. Consumer protection from dangerous products, such as pharmaceutical drugs, has long been such an area. States legislated in this field long before the FDA existed, and state tort actions remain critical in "unconver[ing] unknown drug hazards" by "motivat[ing] injured persons to come forward with information," as well

as compensating those who have suffered injuries. *Id.* at 579. This Court should impose a high barrier against displacing state tort law in a traditionally state-occupied field.

Finally, the district court's decision is in tension with Supreme Court preemption precedent, including the Supreme Court's ruling in this very case. The Court has explained that the judge must determine "whether the relevant federal and state laws irreconcilably conflict," because the "existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *Albrecht*, 139 S. Ct. at 1679 (cleaned up). There is no such irreconcilable conflict here.

Those considerations all counsel against preemption. This Court should reverse.

ARGUMENT

I. Fundamental federalism principles require a narrow view of impossibility preemption

1. The Constitution expressly reserves to the States or the people all powers that are neither delegated to the federal government nor prohibited to the States. See U.S. Const. amend. X. "States thus retain substantial sovereign authority under our constitutional system."

Gregory, 501 U.S. at 457–58. "This federalist structure of joint sovereigns preserves to the people numerous advantages." *Ibid.* Among these advantages, federalism "assures a decentralized government that 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; see also The Federalist 45 ("The powers delegated by the proposed Constitution to the federal government are few and defined. . . . The powers reserved to the several States will extend to all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State.").

Courts undermine those interests when they treat federal law as impliedly preempting state law. This concern may have had less salience in the early years of our Republic, when Congress exercised its power sparingly and 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 Congress now 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.

Congress normally "exert[s] its supremacy by expressly preempting state law, but it may also do so implicitly." *Sikkelee*, 822 F.3d at 687. This Court has recognized implied preemption "in limited circumstances in the doctrine of 'field' preemption," as well as "through conflict preemption." *Id.* at 687–88. Conflict preemption occurs "when a challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of a federal law" (obstacle preemption) or "when a state law conflicts with federal law such that compliance with both state and federal regulations is impossible" (impossibility preemption). *Id.* at 688 (quotation marks omitted).

This Court has properly described preemption as a "precarious" doctrine, because "due respect to our constitutional scheme" of federalism requires "a strong presumption against preemption in areas of the law that States have traditionally occupied." *Id.* at 687. Any preemption analysis thus "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).

This "assumption" has given rise to the presumption against preemption. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). That is, federal courts presume that a federal statute does not preempt conflicting state law unless Congress has made a "plain statement" of its intention to "upset the usual constitutional balance of federal and state powers." *Gregory*, 501 U.S. at 460–61; see also *Sikkelee*, 822 F.3d at 687 ("Congressional intent is the ultimate touchstone of a preemption analysis." (quotation marks omitted)). This presumption against preemption helps preserve the Framers' carefully balanced constitutional design: a federalist system that gives States broad regulatory authority within their territorial jurisdiction except where the Constitution requires otherwise. U.S. Const. amend. X; see *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.").

2. This case illustrates the importance of the presumption. When Congress enacted the FDCA, it was both "awar[e] of the prevalence of state tort litigation" and provided no "federal remedy for consumers

harmed by unsafe or ineffective drugs." *Wyeth*, 555 U.S. at 574. Thus, the Supreme Court concluded in *Albrecht*, "whether Congress' general purpose was to protect consumers, to provide safety-related incentives to manufacturers, or both," the "language, history, and purpose" of the FDCA "all indicate that 'Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.'" 139 S. Ct. at 1677 (quoting *Wyeth*, 555 U.S. at 574–75). Indeed, if "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.

Unable to argue that state-law failure-to-warn tort suits "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" under the FDCA, *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), Defendant-Appellee instead relies on impossibility preemption. Impossibility preemption applies "where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963). But impossibility preemption is a "demanding defense." *Wyeth*, 555 U.S. at 573. A court can conclude that

it was impossible for a drug manufacturer to comply with both federal and state requirements only if there is "clear evidence" that the FDA would not have approved a change to a drug's label that would have addressed the risk, and satisfied the duty, giving rise to the state-law claim. That is, the manufacturer must provide evidence showing that it "fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Albrecht*, 139 S. Ct. at 1672.

The "underlying question for this type of impossibility pre-emption defense" is supposed to be "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. As the Supreme Court has "cautioned many times before," the "possibility of impossibility is not enough." *Ibid.* (cleaned up). Indeed, because a drug manufacturer may typically make labeling changes that add or strengthen a warning without prior FDA approval, "a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both."

Id. at 1679.

Notwithstanding the limited scope of conflict preemption, and that it should have drawn all reasonable inferences in the Plaintiffs-Appellants' favor, see *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986), the district court held that it was "impossible" for Defendant-Appellee simultaneously to comply with state law and with federal law when the FDA's non-final action suggested that it might reject a related, but different, warning. See *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 593 F. Supp. 3d 96 (D.N.J. 2022).

But the warning label that the FDA rejected was about the risk of "stress fractures," not the atypical femoral fractures giving rise to the state-law claims here. *Albrecht*, 139 S. Ct. at 1675. And Defendant-Appellee has not demonstrated that the label change it proposed to the FDA would have satisfied its state law duty to warn. Moreover, the FDA's letter rejecting the proposed label never discusses the atypical femoral fractures at issue here, yet the district court gleaned that the FDA would nonetheless have rejected a label involving these fractures based on informal communication between the company and the agency. *In re Fosamax*, 593 F. Supp. 3d at 133–36.

There is no "clear evidence" that state and federal laws "irreconcilably conflict," nor can Defendant-Appellee be said to have "fully informed the FDA of the justifications for the warning *required by state law*." *Albrecht*, 139 S. Ct. at 1678 (emphasis added). A ruling that allows Defendant-Appellee to prevail under these circumstances would contradict the Supreme Court's clear directive about the narrow scope of impossibility preemption, and undermine the critical role of state tort law in this area. Adopting a sweeping form of impossibility preemption here would flip the presumption against preemption on its head.

II. Regulation of consumer safety is an area of traditional state concern that the presumption against preemption protects

"[I]n all pre-emption cases," courts "start 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 (quotation marks and citations omitted). This is "particularly" so where "Congress has legislated in a field which the States have traditionally occupied." *Ibid.* (citation omitted).

States have long regulated the area of drug labeling. The duty to warn patients and physicians about emerging safety risks predates the advent of federal drug regulation by decades. 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, 37,437 (June 26, 1979) (FDA labeling decisions do not "influence the 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).

With 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 that followed, 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).

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). Although Congress later preempted certain state law requirements for medical devices and vaccines,[1] it never enacted a provision expressly preempting state requirements relating to pharmaceutical labeling. See *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995) (explaining that an express preemption clause "supports a reasonable inference" that Congress "did not intend to pre-empt other matters").

[1] In contrast to the FDCA, which contains no express preemption provision, Congress expressly preempted certain 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 certain state-law regulations of over-the-counter drugs, 21 U.S.C. § 379r(a).

Indeed, the FDA has "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth*, 555 U.S. at 579. State tort suits "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." *Ibid.* They also "serve a distinct compensatory function that may motivate injured persons to come forward with information" about the drug previously unknown to consumers. *Ibid.*

The Supreme Court has explained 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." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989) (quotation marks omitted). Here, the long history of state tort litigation against manufacturers of prescription drugs—and Congress's repeated refusal to amend the FDCA in response—"adds force to" the conclusion that Congress did not intend generally to preempt such litigation. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). Courts thus must be cautious when considering the

preemptive effect of the FDCA, and must avoiding treating a conflict as intractable unless it truly is. This case presents no such intractable conflict that would prevent a pharmaceutical company from complying with state law.

III. The district court's ruling disturbs the balance between state and federal regulation that the Supreme Court has struck

1. The district court's sweeping approach to impossibility preemption could raise a host of other problems. For example, it could create perverse incentives for manufacturers during the development and approval of a new drug. If the FDA's rejection of a proposed warning would bar later tort claims even when the rejection rested on the manufacturer's failure to research thoroughly the problem giving rise to the tort claims, or on evidence of risks unrelated to the tort claims, manufacturers would have an incentive not to conduct adequate research into potential risks. Those are precisely the incentives against which state tort law guards. This approach also could undercut state-law warning requirements that require only constructive (rather than actual) knowledge of risks.[2] And it could create an immunity from state tort

[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

liability based on something that only the manufacturer can ultimately control: what the manufacturer itself knows about a risk. Congress cannot have intended this result, nor can it have intended to preempt state law on this basis—much less "plain[ly]" have done so. *Gregory*, 501 U.S. at 460–61.

The district court's interpretation also could discourage manufacturers from gathering information after the FDA declined to approve a label change. A manufacturer might discover new evidence about a risk after the FDA rejected a label change regarding that risk. The new information could render the FDA's earlier rejection effectively irrelevant. But the district court's ruling might create a high barrier against the use of new evidence of risk when the FDA has previously

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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).

reviewed a proposed label change relating to the risk and rejected it, thus placing great weight on a single, unsuccessful attempt to amend the drug's label even when new risk information should change the FDA's view.[3]

The district court's approach risks creating opportunities for gamesmanship. A manufacturer could obtain state-tort-law immunity by proposing a label change that it knows the FDA will reject based on the available evidence. Then, if the product injures or kills a consumer, and state tort law would impose liability on the manufacturer on the basis of evidence produced at trial, the manufacturer could try to use the failure of this prior inadequate FDA label-change proposal to defeat those tort claims. The *Amici* States have no basis to assess whether that is what happened here. But this Court should not give to the FDCA preemptive effect that could give manufacturers tort immunity through inadequate or overbroad risk warnings.

[3] For example, more than 200 plaintiffs involved in this litigation were injured after the FDA's rejection of Defendant Appellee'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.

The district court's application of preemption in this context vividly illustrates the potential for mischief. The FDA rejected a specific proposed warning. But the district court's reading sweeps more broadly, and would result in preemption whenever a manufacturer proposes to warn about a risk merely because it bears some relation to the one that actually injured a state tort plaintiff. This record does not contain "clear evidence" that the FDA would have rejected a relevant label about the atypical fractures that injured the plaintiffs, as opposed to the "stress fractures" that were the subject of the FDA's rejection. *Albrecht*, 139 S. Ct. at 1672.

The record also lacks "clear evidence" that Defendant-Appellee's proposed label would have satisfied the state-law duty to warn in the first place. If the proposed changes would not have satisfied the state-law duty to warn, the FDA's rejection of *those* changes should not be relevant. 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). If the district court were correct, manufacturers could invoke impossibility preemption even if the label change rejected by the FDA would not have satisfied the state-law duty upon which the plaintiff sued.

This Court should instead hold that a manufacturer cannot demonstrate that compliance with state and federal law are impossible unless the federal regulators did (or clearly would have) rejected a warning that would have satisfied the state-law duty giving rise to the suit.

To guard against this potential gamesmanship, this Court should bear in mind three important principles in reversing the judgment below. First, this Court should require that manufacturers provide comprehensive and specific evidence to the FDA on the issue in question before the FDA's rejection of a label can constitute preemption. Second, this Court should consider the importance of whether any additional evidence of the specific risk came to light after the FDA's decision. And third, this Court should define narrowly the question whether the manufacturer's proposed label would have satisfied the state-law duty to warn in the first place. If the manufacturer has not presented the full scope of available evidence to the agency as to the specific issue at hand; if any evidence post-dating the FDA's decision might have changed the outcome; or if the proposed label change would not have satisfied the relevant state-law duty, the defendant should not be able to invoke impossibility preemption.

2. A theory of "impossibility" preemption that is unmoored from actual impossibility would be nothing more than obstacle preemption. Any such approach cannot be reconciled with the history of drug regulation or basic principles of statutory interpretation, separation of powers, and federalism. Moreover, the Supreme Court has already concluded that "common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA." *Wyeth*, 555 U.S. at 581.

Obstacle preemption would require courts to go beyond the text of a statute to determine the general purpose motivating the enactment. But even if courts could accurately determine the unexpressed purpose underlying a statute, "no legislation pursues its purposes at all costs." *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987) (per curiam); see also *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'"). "Every statute proposes, not only to achieve certain ends, but also to achieve them by particular means—and there is often a considerable legislative battle

over what those means ought to be." *Director, Office of Worker's Compensation Programs, Dep't of Labor v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 136 (1995). Where, as here, Congress has declined to express its intention to preempt state law, this Court should honor Congress's choice of means by declining to imply a broad, unexpressed preemptive effect.

For example, even if one goal of Congress might be to "foster[] uniformity in . . . regulations," that objective is not "unyielding." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 70 (2002). A state tort action that frustrates the goal of uniformity might nonetheless 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 federal regulatory regime.[4] Or an enacted law might reflect a compromise among legislators

[4] 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

balancing the benefits of stricter federal standards 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 the task of divining Congress's unexpressed intent and forecasting a statute's preemptive reach on the basis of that intent, many Justices of the Supreme Court have expressed concern with the scope that this type of preemption would entail. 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

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Bates, 544 U.S. at 451 ("tort suits can serve as a catalyst" to improve industry and federal regulatory practices).

conflict pre-emption based on frustration of purposes"); *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part, concurring in judgment) ("A freewheeling 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."). Other courts of appeals have expressed similar skepticism. See, *e.g.*, *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1045 (9th Cir. 2022) ("The notion that preemption may be 'implied' at all seems oxymoronic, in light of the well-established rule that a 'clear expression' of congressional intent is required to overcome the 'presumption' against implied preemption.").

Here, even if this Court were to apply the incoherent doctrine of implied obstacle preemption, it still would fail. State tort claims are not an obstacle to the FDCA, and "[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. It has not done so. This Court should not override

Congress's choice to withhold preemptive effect from FDA's rejection of a label change merely because it is related to a state tort claim.

* * *

Impossibility preemption is rare, but that is by design. In this context, the Court should require manufacturers to clear a high bar in order to show "clear evidence" that a federal agency prevented it from complying with its state law duty to warn. Requiring anything less would convert impossibility preemption into the disfavored sort of roving "obstacle" preemption.

CONCLUSION

The judgment of the district court should be reversed.

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/s/ Andrew N. Ferguson
Andrew N. Ferguson

Dated: May 30, 2023

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I certify that on May 30, 2023, I electronically filed the foregoing brief with the Clerk of this Court by using the appellate CM/ECF system. The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

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