

THOMAS, J., concurring in judgment

SUPREME COURT OF THE UNITED STATES

No. 06–1249

WYETH, PETITIONER *v.* DIANA LEVINE

ON WRIT OF CERTIORARI TO THE SUPREME COURT OF
VERMONT

[March 4, 2009]

JUSTICE THOMAS, concurring in the judgment.

I agree with the Court that the fact that the Food and Drug Administration (FDA) approved the label for petitioner Wyeth’s drug Phenergan does not pre-empt the state-law judgment before the Court. That judgment was based on a jury finding that the label did not adequately warn of the risk involved in administering Phenergan through the IV-push injection method. Under federal law, without prior approval from the FDA, Wyeth could have “add[ed] or strengthen[ed]” information on its label about “a contraindication, warning, precaution, or adverse reaction,” 21 CFR §314.70(c)(6)(iii)(A) (2008), or “about dosage and administration that is intended to increase the safe use of the drug product,” §314.70(c)(6)(iii)(C), in order to “reflect newly acquired information,” including “new analyses of previously submitted data,” about the dangers of IV-push administration of Phenergan, 73 Fed. Reg. 49603, 49609 (2008). It thus was possible for Wyeth to label and market Phenergan in compliance with federal law while also providing additional warning information on its label beyond that previously approved by the FDA. In addition, federal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA. The Vermont court’s judgment in this case, therefore, did not directly conflict with federal law and is

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not pre-empted.

I write separately, however, because I cannot join the majority's implicit endorsement of far-reaching implied pre-emption doctrines. In particular, I have become increasingly skeptical of this Court's "purposes and objectives" pre-emption jurisprudence. Under this approach, the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law. Because implied pre-emption doctrines that wander far from the statutory text are inconsistent with the Constitution, I concur only in the judgment.

I

A

In order "to ensure the protection of our fundamental liberties," *Atascadero State Hospital v. Scanlon*, 473 U. S. 234, 242 (1985) (internal quotation marks omitted), the "Constitution establishes a system of dual sovereignty between the States and the Federal Government." *Gregory v. Ashcroft*, 501 U. S. 452, 457 (1991). The Framers adopted this "constitutionally mandated balance of power," *Atascadero State Hospital, supra*, at 242, to "reduce the risk of tyranny and abuse from either front," because a "federalist structure of joint sovereigns preserves to the people numerous advantages," such as "a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society" and "increase[d] opportunity for citizen involvement in democratic processes," *Gregory, supra*, at 458. Furthermore, as the Framers observed, the "compound republic of America" provides "a double security . . . to the rights of the people" because "the power surrendered by the people is first divided between two distinct governments, and then the portion allotted to each subdivided among distinct and separate

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departments.” The Federalist No. 51, p. 266 (M. Beloff ed., 2d ed. 1987).

Under this federalist system, “the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause.” *Tafflin v. Levitt*, 493 U. S. 455, 458 (1990). In this way, the Supremacy Clause gives the Federal Government “a decided advantage in [a] delicate balance” between federal and state sovereigns. *Gregory*, 501 U. S., at 460. “As long as it is acting within the powers granted it under the Constitution, Congress may impose its will on the States.” *Ibid.* That is an “extraordinary power in a federalist system.” *Ibid.*

Nonetheless, the States retain substantial sovereign authority. U. S. Const., Amdt. 10 (“The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people”); see also *Alden v. Maine*, 527 U. S. 706, 713 (1999); *Printz v. United States*, 521 U. S. 898, 918–922 (1997); *New York v. United States*, 505 U. S. 144, 155–156 (1992); *Gregory*, *supra*, at 457–459; *Tafflin*, *supra*, at 458. In accordance with the text and structure of the Constitution, “[t]he powers delegated by the proposed constitution to the federal government, are few and defined” and “[t]hose which are to remain in the state governments, are numerous and indefinite.” The Federalist No. 45, at 237–238. Indeed, in protecting our constitutional government, “the preservation of the States, and the maintenance of their governments, are as much within the design and care of the Constitution as the preservation of the Union and the maintenance of the National government.” *Texas v. White*, 7 Wall. 700, 725 (1869), quoted in *New York v. United States*, *supra*, at 162.

As a result, in order to protect the delicate balance of power mandated by the Constitution, the Supremacy Clause must operate only in accordance with its terms.

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The clause provides:

“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.” Art. VI, cl. 2.

With respect to federal laws, then, the Supremacy Clause gives “supreme” status only to those that are “made in Pursuance” of “[t]his Constitution.” *Ibid.*; see 3 J. Story, Commentaries on the Constitution of the United States §1831, p. 694 (1833) (hereinafter Story) (“It will be observed, that the supremacy of the laws is attached to those only, which are made in pursuance of the constitution”).

Federal laws “made in Pursuance” of the Constitution must comply with two key structural limitations in the Constitution that ensure that the Federal Government does not amass too much power at the expense of the States. The first structural limitation, which the parties have not raised in this case, is “the Constitution’s conferral upon Congress of not all governmental powers, but only discrete, enumerated ones.” *Printz, supra*, at 919; see also *United States v. Morrison*, 529 U. S. 598, 618, n. 8 (2000); *New York v. United States, supra*, at 155–157; *McCulloch v. Maryland*, 4 Wheat. 316, 405 (1819) (“This government is acknowledged by all to be one of enumerated powers”).¹

¹This structural limitation may be implicated in a pre-emption case if the federal law at issue is beyond the scope of Congress’ enumerated powers. Expansion of congressional power through an “increasingly generous . . . interpretation of the commerce power of Congress,” for example, creates “a real risk that Congress will gradually erase the diffusion of power between State and Nation on which the Framers

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The second structural limitation is the complex set of procedures that Congress and the President must follow to enact “Laws of the United States.” See *INS v. Chadha*, 462 U. S. 919, 945–946 (1983) (setting forth the Constitution’s Bicameral and Presentment Clauses, Art. I, §7, cls. 2–3, which “prescribe and define the respective functions of the Congress and of the Executive in the legislative process”). “[T]he Framers were acutely conscious that the bicameral requirement and the Presentment Clauses would serve essential constitutional functions,” *Chadha*, 462 U. S., at 951, by allowing the passage of legislation only after it has proceeded through “a step-by-step, deliberate and deliberative process,” *id.*, at 959, that was “finely wrought and exhaustively considered” by the Framers, *id.*, at 951. The Supremacy Clause thus requires that pre-emptive effect be given only those to 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. See 3 J. Story §1831, at 694 (Actions of the Federal Government “which are not pursuant to its constitutional powers, but which are invasions of the residuary authorities of the smaller societies,” are not “the supreme law of the land. They will be merely acts of usurpation, and will deserve to be treated as such”).

B

In light of these constitutional principles, I have become “increasing[ly] reluctan[t] to expand federal statutes beyond their terms through doctrines of implied pre-

based their faith in the efficiency and vitality of our Republic.” *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U. S. 528, 583–584 (1985) (O’Connor, J., dissenting); see also *Marbury v. Madison*, 1 Cranch 137, 176 (1803) (“The powers of the legislature are defined, and limited; and that those limits may not be mistaken, or forgotten, the constitution is written”).

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emption.” *Bates v. Dow Agrosciences LLC*, 544 U. S. 431, 459 (2005) (THOMAS, J., concurring in judgment in part and dissenting in part). My review of this Court’s broad implied pre-emption precedents, particularly its “purposes and objectives” pre-emption jurisprudence, has increased my concerns that implied pre-emption doctrines have not always been constitutionally applied. Under the vague and “potentially boundless” doctrine of “purposes and objectives” pre-emption, *Geier v. American Honda Motor Co.*, 529 U. S. 861, 907 (2000) (STEVENS, J., dissenting), for example, the Court has pre-empted state law based on its interpretation of broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law. See, e.g., *Pharmaceutical Research and Mfrs. of America v. Walsh*, 538 U. S. 644, 678 (2003) (THOMAS, J., concurring in judgment) (referring to the “concomitant danger of invoking obstacle pre-emption based on the arbitrary selection of one purpose to the exclusion of others”); *Crosby v. National Foreign Trade Council*, 530 U. S. 363, 388–391 (2000) (SCALIA, J., concurring in judgment) (criticizing the majority’s reliance on legislative history to discern statutory intent when that intent was “perfectly obvious on the face of th[e] statute”); *Geier, supra*, at 874–883 (relying on regulatory history, agency comments, and the Government’s litigating position to determine that federal law pre-empted state law).

Congressional and agency musings, however, do not satisfy the Art. I, §7 requirements for enactment of federal law and, therefore, do not pre-empt state law under the Supremacy Clause. When analyzing the pre-emptive effect of federal statutes or regulations validly promulgated thereunder, “[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [provision] at issue” to comply with the Constitution. *CSX Transp., Inc. v. Easterwood*, 507 U. S. 658, 664 (1993); see

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also *New York v. FERC*, 535 U. S. 1, 18 (2002) (“[A] federal agency may pre-empt state law only when and if it is acting within the scope of its congressional delegated authority . . . [for] an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it” (internal quotation marks omitted; second alteration in original)); *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U. S. 564, 617 (1997) (THOMAS, J., dissenting) (noting that “treating unenacted congressional intent as if it were law would be constitutionally dubious”). Pre-emption analysis should not be “a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict.” *Bates, supra*, at 459 (THOMAS, J., concurring in judgment in part and dissenting in part) (internal quotation marks and citation omitted); see also *Geier, supra*, at 911 (STEVENS, J., dissenting) (“[P]re-emption analysis is, or at least should be, a matter of precise statutory [or regulatory] construction rather than an exercise in free-form judicial policymaking” (internal quotation marks omitted)). Pre-emption must turn on whether state law conflicts with the text of the relevant federal statute or with the federal regulations authorized by that text. See *Foster v. Love*, 522 U. S. 67, 71 (1997) (finding that conflict pre-emption question “turn[ed] entirely on the meaning of the state and federal statutes” at issue before the Court); see also *New York v. FERC, supra*, at 19.

II

This Court has determined that there are two categories of conflict pre-emption, both of which Wyeth contends are at issue in this case. First, the Court has found pre-emption “where compliance with both federal and state regulations is a physical impossibility for one engaged in

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interstate commerce.” *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U. S. 132, 142–143 (1963). Second, the Court has determined that federal law pre-empts state law when, “under the circumstances of [a] particular case, [state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941).²

A

Wyeth first contends that “it would have been impossible for it to comply with the state-law duty to modify Phenergan’s labeling without violating federal law.” *Ante*, at 6 (opinion for the Court by STEVENS, J.). But, as the majority explains, the text of the relevant federal statutory provisions and the corresponding regulations do not directly conflict with the state-law judgment before us.

This Court has used different formulations of the standard to be used in deciding whether state and federal law conflict, and thus lead to pre-emption, under the “impossibility” doctrine. See, e.g., *Geier, supra*, at 873 (“a case in which state law penalizes what federal law requires”); *American Telephone & Telegraph Co. v. Central Office Telephone, Inc.*, 524 U. S. 214, 227 (1998) (*AT&T*) (when state-law claims “directly conflict” with federal law), cited in *Geier, supra*, at 874 (describing *AT&T* as a “cas[e] involving impossibility”); *Florida Lime & Avocado Growers, supra*, at 142–143 (“where compliance with both fed-

²The majority’s pre-emption analysis relies in part on a presumption against pre-emption. *Ante*, at 8, and n. 3 (opinion of STEVENS, J.). Because it is evident from the text of the relevant federal statutes and regulations themselves that the state-law judgment below is not pre-empted, it is not necessary to decide whether, or to what extent, the presumption should apply in a case such as this one, where Congress has not enacted an express-pre-emption clause. Cf. *Altria Group, Inc. v. Good*, 555 U. S. ___, ___ (2008) (THOMAS, J., dissenting) (rejecting the use of a presumption against pre-emption in express pre-emption cases).

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eral and state regulations is a physical impossibility”). The Court has generally articulated a very narrow “impossibility standard,” see *Crosby*, 530 U. S., at 372–373 (citing *Florida Lime & Avocado Growers, supra*, at 142–143); see also *Sprietsma v. Mercury Marine*, 537 U. S. 51, 64–65 (2002); *United States v. Locke*, 529 U. S. 89, 109 (2000)—in part because the overly broad sweep of the Court’s “purposes and objectives” approach, see *infra*, at 13–23, has rendered it unnecessary for the Court to rely on “impossibility” pre-emption.

The Court, in fact, has not explained why a narrow “physical impossibility” standard is the best proxy for determining when state and federal laws “directly conflict” for purposes of the Supremacy Clause. There could be instances where it is not “physically impossible” to comply with both state and federal law, even when the state and federal laws give directly conflicting commands. See Nelson, Preemption, 86 Va. L. Rev. 225, 260–261 (2000). For example, if federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior. *Ibid.* Therefore, “physical impossibility” may not be the most appropriate standard for determining whether the text of state and federal laws directly conflict. See *ibid.* (concluding that the Supremacy Clause does not limit direct conflicts to cases with “physically impossible” conflicts and arguing that evidence from the Founding supports a standard of “logical-contradiction”); see also *AT&T, supra*, at 227 (requiring that the state-law claims “directly conflict” with federal law); 3 Story §1836, at 701 (suggesting instead that a state law is pre-empted by the Supremacy Clause when it is “repugnant to the constitution of the United States” (emphasis added)).

Nonetheless, whatever the precise constitutional con-

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tours of implied pre-emption may be, I am satisfied that it does not operate against respondent's judgment below. The text of the federal laws at issue do not require that the state-court judgment at issue be pre-empted, under either the narrow "physical impossibility" standard, *Florida Lime & Avocado Growers, supra*, at 142–143, or a more general "direc[t] conflict" standard, *AT&T, supra*, at 227.

Under the FDA's "changes being effected" regulation, 21 CFR §314.70(c)(6)(iii), which was promulgated pursuant to the FDA's statutory authority, it is physically possible for Wyeth to market Phenergan in compliance with federal and Vermont law. As the majority explains, Wyeth could have changed the warning on its label regarding IV-push without violating federal law. See *ante*, at 11–13. The "changes being effected" regulation allows drug manufacturers to change their labels without the FDA's preapproval if the changes "add or strengthen a contraindication, warning, precaution, or adverse reaction," §314.70(c)(6)(iii)(A), or "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," §314.70(c)(6)(iii)(C), in order to "reflect newly acquired information," including "new analyses of previously submitted data," 73 Fed. Reg. 49603, 49609. Under the terms of these regulations, after learning of new incidences of gangrene-induced amputation resulting from the IV-push administration of Phenergan, see *ante*, at 12–13, federal law gave Wyeth the authority to change Phenergan's label to "strengthen a . . . warning," "strengthen a . . . precaution," §314.70(c)(6)(iii)(A), or to "strengthen an instruction about . . . administration [of the IV-push method] . . . to increase the safe use of the drug product," §314.70(c)(6)(iii)(C). Thus, it was physically possible for Wyeth to comply with a state-law requirement to provide stronger warnings on Phenergan about the risks of the IV-push administration method

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while continuing to market Phenergan in compliance with federal law.

In addition, the text of the statutory provisions governing FDA drug labeling, and the regulations promulgated thereunder, do not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA. Thus, there is no “direct conflict” between the federal labeling law and the state-court judgment. The statute prohibits the interstate marketing of any drug, except for those that are federally approved. See 21 U. S. C. §355(a) (“*No person shall* introduce or deliver for introduction into interstate commerce any new drug, *unless* an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug” (emphasis added)). To say, as the statute does, that Wyeth may not market a drug without federal approval (*i.e.*, without an FDA-approved label) is not to say that federal approval gives Wyeth the unfettered right, for all time, to market its drug with the specific label that was federally approved. Initial approval of a label amounts to a finding by the FDA that the label is safe for purposes of gaining federal approval to market the drug. It does not represent a finding that the drug, as labeled, can never be deemed unsafe by later federal action, or as in this case, the application of state law.

Instead, FDA regulations require a drug manufacturer—after initial federal approval of a drug’s label—to revise the federally approved label “to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.” 21 CFR §201.80(e). Drug manufacturers are also required to “establish and maintain records and make reports” to the FDA about “[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related,” after it has received federal approval. §§314.80(a), (c), (j). In addition,

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the manufacturer must make periodic reports about “adverse drug experience[s]” associated with its drug and include “a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).” §§314.80(c)(2)(i)–(ii). When such records and reports are not made, the FDA can withdraw its approval of the drug. §314.80(j); see also 21 U. S. C. §355(e) (“The Secretary may . . . withdraw the approval of an application . . . if the Secretary finds . . . that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports”). The FDA may also determine that a drug is no longer safe for use based on “clinical or other experience, tests, or other scientific data.” *Ibid.* (approval may be withdrawn if “the Secretary finds . . . that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved”).

The text of the statutory provisions and the accompanying regulatory scheme governing the FDA drug approval process, therefore, establish that the FDA’s initial approval of a drug is not a guarantee that the drug’s label will never need to be changed. And nothing in the text of the statutory or regulatory scheme necessarily insulates Wyeth from liability under state law simply because the FDA has approved a particular label.

In sum, the relevant federal law did not give Wyeth a right that the state-law judgment took away, and it was possible for Wyeth to comply with both federal law and the Vermont-law judgment at issue here. The federal statute and regulations neither prohibited the stronger warning label required by the state judgment, nor insulated Wyeth from the risk of state-law liability. With no “direct conflict” between the federal and state law, then, the state-law judgment is not pre-empted. Cf. *AT&T*, 524 U. S., at

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221–226 (finding pre-emption where federal law forbade common carriers from extending communications privileges requested by state-law claims); *Foster*, 522 U. S., at 68–69 (finding pre-emption where the federal statute required congressional elections on a particular date different from that provided by state statute).

B

Wyeth also contends that state and federal law conflict because “recognition of [this] state tort action creates an unacceptable ‘obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’ *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941), because it substitutes a lay jury’s decision about drug labeling for the expert judgment of the FDA.” *Ante*, at 6–7. This Court’s entire body of “purposes and objectives” pre-emption jurisprudence is inherently flawed. The cases improperly rely on legislative history, broad atextual notions of congressional purpose, and even congressional inaction in order to pre-empt state law. See *supra*, at 5–7. I, therefore, cannot join the majority’s analysis of this claim, see *ante*, at 17–25, or its reaffirmation of the Court’s “purposes and objectives” jurisprudence, *ante*, at 17–18 (analyzing congressional purposes); *ante*, at 20 (quoting the “‘purposes and objectives’” pre-emption standard from *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941), and *Geier*, 529 U. S., at 883); *ante*, at 23–24, and nn. 13–14 (analyzing this case in light of *Geier*, 529 U. S. 861).

1

The Court first formulated its current “purposes and objectives” pre-emption standard in *Hines* when it considered whether the federal Alien Registration Act pre-empted an Alien Registration Act adopted by the Commonwealth of Pennsylvania. The Court did not find that the two statutes, by their terms, directly conflicted. See

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Hines, supra, at 59–60, and n. 1 (citing Pa. Stat. Ann., Tit. 35, §§1801–1806 (Purdon Supp. 1940)); 312 U. S., at 60, and n. 5 (citing Act of June 28, 1940, 54 Stat. 670); 312 U. S., at 69–74 (analyzing numerous extratextual sources and finding pre-emption without concluding that the terms of the federal and state laws directly conflict); see also *id.*, at 78 (noting that “[i]t is conceded that the federal act in operation does not at any point conflict with the state statute” (Stone, J., dissenting)).³ Nonetheless, the Court determined that it was not confined to considering merely the terms of the relevant federal law in conducting its pre-emption analysis. Rather, it went on to ask whether the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Id.*, at 67.

In so doing, the Court looked far beyond the relevant federal statutory text and instead embarked on its own

³ According to the Court, the Pennsylvania Act required:

“every alien 18 years or over, with certain exceptions, to register once each year; provide such information as is required by the statute, plus any ‘other information and details’ that the Department of Labor and Industry may direct; pay \$1 as an annual registration fee; receive an alien identification card and carry it at all times; show the card whenever it may be demanded by any police officer or any agent of the Department of Labor and Industry; and exhibit the card as a condition precedent to registering a motor vehicle in his name or obtaining a license to operate one. . . . Nonexempt aliens who fail to register are subject to a fine . . . or imprisonment For failure to carry an identification card or for failure to show it upon proper demand, the punishment is a fine . . . or imprisonment” *Hines*, 312 U. S., at 59–60 (footnote omitted).

The Court explained that the federal Alien Registration Act required:

“a single registration of aliens 14 years of age and over; detailed information specified by the Act, plus ‘such additional matters as may be prescribed by the Commissioner, with the approval of the Attorney General’; finger-printing of all registrants; and secrecy of the federal files No requirement that aliens carry a registration card to be exhibited to police or others is embodied in the law, and only the wilful failure to register is made a criminal offense” *Id.*, at 60–61.

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freeranging speculation about what the purposes of the federal law must have been. See *id.*, at 69–74. In addition to the meaning of the relevant federal text, the Court attempted to discern “[t]he nature of the power exerted by Congress, the object sought to be attained, and the character of the obligations imposed by the law.” *Id.*, at 70. To do so, the Court looked in part to public sentiment, noting that “[o]pposition to laws . . . singling out aliens as particularly dangerous and undesirable groups, is deep-seated in this country.” *Ibid.* The Court also relied on statements by particular Members of Congress and on congressional inaction, finding it pertinent that numerous bills with requirements similar to Pennsylvania’s law had failed to garner enough votes in Congress to become law. *Id.*, at 71–73, and nn. 32–34. Concluding that these sources revealed a federal purpose to “protect the personal liberties of law-abiding aliens through one uniform national registration system,” the Court held that the Pennsylvania law was pre-empted. *Id.*, at 74.

Justice Stone, in dissent, questioned the majority’s decision to read an exclusive registration system for aliens into a statute that did not specifically provide such exclusivity. See *id.*, at 75. He noted his concern that state power would be improperly diminished through a pre-emption doctrine driven by the Court’s “own conceptions of a policy which Congress ha[d] not expressed and which is not plainly to be inferred from the legislation which it ha[d] enacted.” *Ibid.* In his view, nothing that Congress enacted had “denie[d] the states the practicable means of identifying their alien residents and of recording their whereabouts.” *Id.*, at 78. Yet, the *Hines* majority employed pre-emption to override numerous state alien-registration laws even though enacted federal law “at no point conflict[ed] with the state legislation and [was]

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harmonious with it.” *Id.*, at 79.⁴

2

The consequences of this Court’s broad approach to “purposes and objectives” pre-emption are exemplified in this Court’s decision in *Geier*, which both the majority and the dissent incorporate into their analysis today. See *ante*, at 23–24, and nn. 13–14; *post*, at 6–9 (opinion of ALITO, J.). In *Geier*, pursuant to the National Traffic and Motor Vehicle Safety Act of 1966 (Safety Act), 80 Stat. 718, 15 U. S. C. §1381 *et seq.* (1988 ed.), the Department of Transportation (DOT) had promulgated a Federal Motor Vehicle Safety Standard that “required auto manufacturers to equip some but not all of their 1987 vehicles with passive restraints.” 529 U. S., at 864–865. The case required this Court to decide whether the Safety Act pre-empted a state common-law tort action in which the plaintiff claimed that an auto manufacturer, though in compliance with the federal standard, should nonetheless have equipped a 1987 automobile with airbags. *Id.*, at 865. The Court first concluded that the Safety Act’s express pre-emption provision and its saving clause, read together, did not expressly pre-empt state common-law claims. See *id.*, at 867–868.⁵

⁴According to Justice Stone, the *Hines* majority’s analysis resembled an inquiry into whether the federal act “‘occupied the field,’” rather than an application of simple conflict pre-emption principles. *Id.*, at 78 (dissenting opinion). Regardless of whether *Hines* involved field or conflict pre-emption, the dissent accurately observed that in assessing the boundaries of the federal law—*i.e.*, the scope of its pre-emptive effect—the Court should look to the federal statute itself, rather than speculate about Congress’ unstated intentions. *Id.*, at 78–79. See also *Camps Newfoundland/Owatonna, Inc. v. Town of Harrison*, 520 U. S. 564, 616–617 (1997) (THOMAS, J., dissenting) (noting that “field pre-emption is itself suspect, at least as applied in the absence of a congressional command that a particular field be pre-empted”).

⁵The Safety Act’s express pre-emption provision stated in part:

“Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State . . . shall have any authority

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The Court then proceeded to consider whether the state action was nonetheless pre-empted as an “obstacle” to the purposes of the federal law. The Court held that the state tort claim was pre-empted, relying in large part on comments that DOT made when promulgating its regulation, statements that the Government made in its brief to the Court, and regulatory history that related to the federal regulation of passive restraints. See *id.*, at 874–886.

In particular, the majority found that DOT intended to “deliberately provid[e] the manufacturer[s] with a range of choices among different passive restraint devices” and to “bring about a mix of different devices introduced gradually over time,” based on comments that DOT made when promulgating its regulation, rather than the Safety Act’s text. *Id.*, at 875. The majority also embarked on a judicial inquiry into “why and how DOT sought these objectives,” *ibid.*, by considering regulatory history and the Government’s brief, which described DOT’s safety standard as “‘embod[ying] the Secretary’s policy judgment that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car,’” *id.*, at 881 (quoting Brief for United States as *Amicus Curiae* in *Geier v. American Honda Motor Co.*, O. T. 1999, No. 98–1811, p. 25); see also

either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment[,] any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.” 15 U. S. C. §1392(d) (1988 ed.).

The Safety Act also included a saving clause, which stated: “Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.” §1397(k). The majority and dissent in *Geier* agreed that the import of the express pre-emption provision and the saving clause, read together, was that by its terms, the Safety Act did not expressly pre-empt state common-law actions. See *Geier*, 529 U. S., at 867–868; *id.*, at 895–898 (STEVENS, J., dissenting).

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529 U. S., at 883–884. Based on this “*ex post* administrative litigating position and inferences from regulatory history and final commentary,” *id.*, at 910–911 (STEVENS, J., dissenting), the Court found that the state action was pre-empted because it would have required manufacturers of all cars similar to that in which the plaintiff was injured to “install airbags rather than other passive restraint systems” and would have, therefore, “presented an obstacle to the variety and mix of devices that the federal regulation sought” to phase in gradually, *id.*, at 881.

The Court’s decision in *Geier* to apply “purposes and objectives” pre-emption based on agency comments, regulatory history, and agency litigating positions was especially flawed, given that it conflicted with the plain statutory text of the saving clause within the Safety Act, which explicitly preserved state common-law actions by providing that “[c]ompliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law,” 15 U. S. C. §1397(k) (1988 ed.).⁶ See *Engine Mfrs. Assn. v.*

⁶In addition to the impropriety of looking beyond the plain text of the saving clause to regulatory history, DOT comments, and an administrative litigating position to evaluate the Safety Act’s pre-emptive effect, it is unclear that the Court in *Geier* accurately assessed the federal objectives of the relevant federal law. As the dissent in *Geier* pointed out, the purpose of the Safety Act, as stated by Congress, was generally “to reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents.” *Id.*, at 888–889 (opinion of STEVENS, J.) (quoting 15 U. S. C. §1381 (1988 ed.)). On its face, that goal is of course consistent with a state-law judgment that a particular vehicle needed a passive restraint system that would better protect persons from death and injury during traffic accidents. Furthermore, the dissent observed that “by definition all of the standards established under the Safety Act . . . impose minimum, rather than fixed or maximum, requirements.” 529 U. S., at 903 (citing 15 U. S. C. §1391(2) (1988 ed.)). Thus, in the dissent’s view, the requirements of the DOT regulation were not ceilings, and it was “obvious that the Secretary favored a more rapid increase” than required by the regulations. 529 U. S., at 903. That

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South Coast Air Quality Management Dist., 541 U. S. 246, 252 (2004) (“Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose” (internal quotation marks omitted)); *West Virginia Univ. Hospitals, Inc. v. Casey*, 499 U. S. 83, 98 (1991) (“The best evidence of th[e] purpose [of a statute] is the statutory text adopted by both Houses of Congress and submitted to the President”). In addition, the Court’s reliance on its divined purpose of the federal law—to gradually phase in a mix of passive restraint systems—in order to invalidate a State’s imposition of a greater safety standard was contrary to the more general express statutory goal of the Safety Act “to reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents,” 15 U. S. C. §1381 (1988 ed.). This Court has repeatedly stated that when statutory language is plain, it must be enforced according to its terms. See *Jimenez v. Quarterman*, 555 U. S. ____ (2009); see also, e.g., *Dodd v. United States*, 545 U. S. 353, 359 (2005); *Lamie v. United States Trustee*, 540 U. S. 526, 534 (2004); *Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A.*, 530 U. S. 1, 6 (2000). The text in *Geier* “directly addressed the precise question at issue” before the Court, so that should have been “the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *National Assn. of Home Builders v. Defenders of Wildlife*, 551 U. S. 644, ____ (2007) (slip op., at 18) (2007) (internal quotation marks omitted). With text that allowed state actions like the one at issue in *Geier*, the Court had no authority to comb through agency commentaries to find a basis for an alternative conclusion.

goal also would be consistent with a state-law judgment finding that a manufacturer acted negligently when it failed to include an airbag in a particular car. See *id.*, at 903–904.

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Applying “purposes and objectives” pre-emption in *Geier*, as in any case, allowed this Court to vacate a judgment issued by another sovereign based on nothing more than assumptions and goals that were untethered from the constitutionally enacted federal law authorizing the federal regulatory standard that was before the Court. See *Watters v. Wachovia Bank, N.A.*, 550 U. S. 1, 44 (2007) (STEVENS, J., dissenting) (noting that pre-emption “affects the allocation of powers among sovereigns”). “[A]n agency literally has no power to act, let alone pre-empt the [law] of a sovereign State, unless and until Congress confers power upon it.” *New York v. FERC*, 535 U. S., at 18 (quoting *Louisiana Pub. Serv. Comm’n v. FCC*, 476 U. S. 355, 374 (1986)). Thus, no agency or individual Member of Congress can pre-empt a State’s judgment by merely musing about goals or intentions not found within or authorized by the statutory text. See *supra*, at 5–7.

The Court’s “purposes and objectives” pre-emption jurisprudence is also problematic because it encourages an overly expansive reading of statutory text. The Court’s desire to divine the broader purposes of the statute before it inevitably leads it to assume that Congress wanted to pursue those policies “at all costs”—even when the text reflects a different balance. See *Geier, supra*, at 904 (STEVENS, J., dissenting) (finding no evidence to support the notion that the DOT Secretary intended to advance the purposes of the safety standard “at all costs”); Nelson, 86 Va. L. Rev., at 279–280. As this Court has repeatedly noted, “it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute’s primary objective must be the law.” *E.g., Norfolk Southern R. Co. v. Sorrell*, 549 U. S. 158, 171 (2007) (quoting *Rodriguez v. United States*, 480 U. S. 522, 526 (1987) (*per curiam*)). Federal legislation is often the result of compromise between legislators and “groups with marked but divergent interests.” See *Ragsdale v. Wolver-*

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ine World Wide, Inc., 535 U. S. 81, 93–94 (2002). Thus, a statute’s text might reflect a compromise between parties who wanted to pursue a particular goal to different extents. See, *e.g.*, *ibid.* (noting that the Family and Medical Leave Act’s provision of only 12 workweeks of yearly leave “was the result of compromise” that must be given effect by courts); *Silkwood v. Kerr-McGee Corp.*, 464 U. S. 238, 257 (1984) (finding that a state law was not pre-empted though it allegedly frustrated a primary purpose of the Atomic Energy Act because the Act provided that its purpose was to be furthered only “to the extent it is consistent ‘with the health and safety of the public’” (quoting 42 U. S. C. §2013(d) (1982 ed.))); see also Manning, What Divides Textualists from Purposivists? 106 Colum. L. Rev. 70, 104 (2006) (“Legislators may compromise on a statute that does not fully address a perceived mischief, accepting half a loaf to facilitate a law’s enactment”). Therefore, there is no factual basis for the assumption underlying the Court’s “purposes and objectives” pre-emption jurisprudence that every policy seemingly consistent with federal statutory text has necessarily been authorized by Congress and warrants pre-emptive effect. Instead, our federal system in general, and the Supremacy Clause in particular, accords pre-emptive effect to only those policies that are actually authorized by and effectuated through the statutory text.

3

The majority, while reaching the right conclusion in this case, demonstrates once again how application of “purposes and objectives” pre-emption requires inquiry into matters beyond the scope of proper judicial review. For example, the majority relies heavily on Congress’ failure “during the . . . 70-year history” of the federal Food, Drug, and Cosmetic Act to enact an express pre-emption provision that addresses approval of a drug label by the FDA.

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Ante, at 18. That “silence on the issue, coupled with [Congress] certain awareness of the prevalence of state tort litigation,” the majority reasons, is evidence that Congress did not intend for federal approval of drug labels to preempt state tort judgments. *Ibid.*; see also *ante*, at 17–18 (construing from inaction that Congress “[e]vidently [had] determined that widely available state rights of action provided appropriate relief”). Certainly, the absence of a statutory provision pre-empting all state tort suits related to approved federal drug labels is pertinent to a finding that such lawsuits are not pre-empted. But the relevance is in the fact that no statute explicitly pre-empts the lawsuits, and not in any inferences that the Court may draw from congressional silence about the motivations or policies underlying Congress’ failure to act. See *Brown v. Gardner*, 513 U. S. 115, 121 (1994) (“[C]ongressional silence lacks persuasive significance” (internal quotation marks omitted)); *O’Melveny & Myers v. FDIC*, 512 U. S. 79, 85 (1994) (“[M]atters left unaddressed in [a comprehensive and detailed federal] scheme are presumably left subject to the disposition provided by state law”); *Camps Newfound*, 520 U. S., at 616 (“[O]ur pre-emption jurisprudence explicitly rejects the notion that mere congressional silence on a particular issue may be read as pre-empting state law”).

In this case, the majority has concluded from silence that Congress believed state lawsuits pose no obstacle to federal drug-approval objectives. See *ante*, at 18. That is the required conclusion, but only because it is compelled by the text of the relevant statutory and regulatory provisions, not judicial suppositions about Congress’ unstated goals. The fact that the Court reaches the proper conclusion does not justify its speculation about the reasons for congressional inaction. In this case, the Court has relied on the perceived congressional policies underlying inaction to find that state law is *not* pre-empted. But once the

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Court shows a willingness to guess at the intent underlying congressional inaction, the Court could just as easily rely on its own perceptions regarding congressional inaction to give unduly broad pre-emptive effect to federal law. See, e.g., *American Ins. Assn. v. Garamendi*, 539 U. S. 396, 401, 405–408, 429 (2003) (finding that Congress’ failure to pass legislation indicating that it disagreed with the President’s executive agreement supported, at least in part, the Court’s determination that the agreement pre-empted state law). Either approach is illegitimate. Under the Supremacy Clause, state law is pre-empted only by federal law “made in Pursuance” of the Constitution, Art. VI, cl. 2—not by extratextual considerations of the purposes underlying congressional inaction. See *Hoffman v. Connecticut Dept. of Income Maintenance*, 492 U. S. 96, 104 (1989) (plurality opinion) (finding that policy arguments that “are not based in the text of the statute . . . are not helpful”); *TVA v. Hill*, 437 U. S. 153, 194 (1978) (“Our individual appraisal of the wisdom or unwisdom of a particular course consciously selected by the Congress is to be put aside in the process of interpreting a statute”). Our role, then, is merely “to interpret the language of the statute[s] enacted by Congress.” *Barnhart v. Sigmon Coal Co.*, 534 U. S. 438, 461 (2002).

III

The origins of this Court’s “purposes and objectives” pre-emption jurisprudence in *Hines*, and its broad application in cases like *Geier*, illustrate that this brand of the Court’s pre-emption jurisprudence facilitates freewheeling, extratextual, and broad evaluations of the “purposes and objectives” embodied within federal law. This, in turn, leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution and the agency actions authorized thereby.

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Because such a sweeping approach to pre-emption leads to the illegitimate—and thus, unconstitutional—invalidation of state laws, I can no longer assent to a doctrine that pre-empts state laws merely because they “stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives” of federal law, *Hines*, 312 U. S., at 67, as perceived by this Court. I therefore respectfully concur only in the judgment.