No. 06-1249

IN THE

Supreme Court of the United States

WYETH,
Petitioner,
v.
DIANA LEVINE,
Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF OF THE CENTER FOR STATE ENFORCEMENT OF ANTITRUST AND CONSUMER PROTECTION LAWS, INC. AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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IDENTITY AND INTEREST OF *AMICUS CURIAE*[1]

The Center for State Enforcement of Antitrust and Consumer Protection Laws, Inc. is a nonprofit public interest and research organization. Its mission is to

[1] The parties' letters of consent to the filing of this brief have been filed with the Clerk. No counsel for a party in this case authored this brief in whole or in part, and no person or entity, other than amicus or its counsel, made a monetary contribution to the brief's preparation or submission.

enhance consumer welfare by supporting the fair, effective, and uniform enforcement of antitrust and consumer protection laws at the state level. Among other things, it provides grants to assist in multi-state investigations of price fixing, identity theft and other consumer protection issues; offers educational assistance grants for officials in state attorney general offices; and facilitates access for State Attorneys General to economists with expertise in industrial organization and consumer protection issues.

The Center is concerned that an aggressive program of preemption of state laws by federal regulatory agencies will result in inadequate protection of consumers under state product liability and consumer protection laws. The position of the petitioner and many of its *amici* in this case, including the United States, reflects a broader movement in which federal administrative agencies have joined forces with regulated industries to urge preemption of state tort and consumer protection laws.[2] The Center filed a brief *amicus curiae* in *Watters v. Wachovia Bank, N.A.*, 127 S.Ct. 1559 (2007), addressing the question of what deference courts should afford administrative agencies on questions of preemption.

STATEMENT

Petitioner makes no general claim for deference to agency views about preemption. Likewise, the United States, as *amicus curiae* supporting petitioner, says the Court "need not rely on deference to FDA's views" in order to find preemption (U.S. Brf. at

[2] *See* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007).

26). Nevertheless, the submissions of petitioner and its *amici* rest critically on claims of deference to the views of the Federal Food and Drug Administration (FDA). These claims of deference must be confronted on their own terms. Doing so requires a determination of the proper role of agencies in resolving preemption questions.

Petitioner's first claim is based on the "impossibility" of complying with both federal drug labeling law and Vermont failure-to-warn products liability law. The Vermont Supreme Court rejected this claim, pointing to an FDA regulation (the so-called changes being effected (or CBE) regulation) which plainly permits a pharmaceutical manufacturer to make labeling changes without advance FDA approval, provided those changes "add or strengthen" safety warnings. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A) and (C). In an effort to circumvent the plain meaning of this regulation, petitioner and its *amici* ask the Court to defer to a recent FDA "interpretation" of that regulation which would make it applicable only to changes motivated by new data or studies. Other than some statements made by the FDA in regulatory preambles, however, the only authoritative source for this interpretation is a *proposed* regulation issued by the FDA in January of 2008. *See Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 Fed. Reg. 2848 (2008). In short, the impossibility preemption claim rests on a claim of deference to a recent FDA interpretation that significantly limits the scope of a longstanding FDA regulation, does not have the force of law, and was not promulgated in a process that permits public participation.

Petitioner's second claim is that the application of Vermont failure-to-warn law would frustrate the purposes of the Federal Food Drug and Cosmetic Act (FDCA or Act). State tort liability, however, has long co-existed with federal food and drug regulation. *See Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1019 & n.16 (2008) (Ginsburg, J., dissenting) (collecting authorities). The "frustration" identified by petitioner comes about only because of a novel interpretation of the new drug provisions of the Act, namely, that the Act imposes not just a "floor" on information disclosure but also a "ceiling." The source of this floor-and-ceiling interpretation is not any clear language found in the Act itself. Rather, it is an interpretation recently advanced by the FDA, most prominently in a Federal Register notice of 2006. *See Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, 71 Fed. Reg. 3922, 3933-36 (2006) (hereinafter, "Preemption Preamble"). This theory, again, significantly modifies the longstanding understanding of the Act, does not have the force of law, and was not promulgated in a way that would allow meaningful comment by affected interests.

SUMMARY OF ARGUMENT

The proper role of federal administrative agencies in preemption presents a number of vexing questions, and this Court has understandably been cautious in supplying answers. Three distinct questions can be identified. (1) When can administrative action serve as the basis for a judgment by a court that preemption is required? (2) When can administrative agencies preempt state law on their own authority? (3) What deference or weight should courts give to opinions by administrative agencies about the preemptive effect of federal law? The third question, in

particular, is presented by this case. But the first and second questions are also implicated.

We believe that careful attention to the language and drafting history of the Supremacy Clause, together with considerations of comparative institutional advantage, suggest the following answers. First, agency action can serve as the basis for a judgment of preemption by a court only when the agency acts with the force of law. Agency action that is merely advisory or that does no more than state an agency's legal opinion is not a "Law of the United States," and hence cannot serve as the basis for a judicial finding of preemption. Second, agencies can preempt state law on their own authority only when Congress, acting through the Necessary and Proper Clause, has expressly delegated authority to the agency to preempt, and the agency, in a proper exercise of this authority, has acted with the force of law. Third, unless Congress has expressly delegated authority to preempt, agency statements of opinion about the preemptive effect are entitled to no deference by courts. Courts should look to agencies for guidance on critical issues of legislative fact, most notably the practical impact of diverse state standards on a federal regulatory scheme. When agencies make reasoned determinations of such issues of legislative fact, they are entitled to "weight," especially if the agency has afforded States and other concerned parties a full opportunity to provide input through notice and comment proceedings or otherwise. As to the ultimate legal issue of preemption, however, courts should exercise independent judgment.

As applied to this case, these principles require that the FDA be given no deference on the question

whether the FDCA incorporates a floor or a floor-and-ceiling on the information that drug manufacturers must disclose. Congress has not delegated authority to the FDA to preempt, and the FDA's interpretation has not been adopted in a format that has the force of law. The FDA has offered its opinion that the Act requires preemption of state duty to warn laws. But its reason for preferring a federal monopoly is its own stated belief—undoubtedly shared by every federal agency—that its views are sounder than those of state judges and juries. This argument, however, sheds no light on whether federal standards should be exclusive. Congress could have agreed with the FDA's assessment of its superior competence, and yet still have preferred to perpetuate regulatory competition over appropriate standards, or to preserve state law as a source of compensation for tort victims.

The FDA is also entitled to no deference for its interpretation of the CBE regulation permitting manufacturers to make stronger warnings without advance FDA approval. If the FDA cannot preempt state law directly, it should not be allowed to do so indirectly though the device of "interpreting" a regulation that is otherwise plain on its face.

ARGUMENT

I. THIS COURT HAS CAREFULLY AVOIDED DEFERRING TO ADMINISTRATIVE AGENCIES' VIEWS ON PREEMPTION

Federal administrative action can be relevant to preemption in different ways. It is well established that agency action which has the force of law, such as a legislative regulation, can serve as a source of a

preemption determination *by a court*.[3] There is also little doubt that, in the relatively rare circumstance where Congress has *expressly delegated* authority to an agency to issue preemptive regulations, agencies can preempt state law on their own authority.[4] The principal question here is distinct and is controversial: how much, if any, deference should courts give to statements of agency *opinion* about the preemptive force of federal law? The question has been presented in several recent preemption cases. The Court has, with good reason, carefully avoided any suggestion that agencies are entitled to some general level of deference on preemption questions, whether it be

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[3] *See, e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867–68 (2000) (holding that regulation mandating phase-in of passive restraints in automobiles impliedly preempts state tort law claim based on proposition that air bags are mandatory); *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 674–75 (1993) (holding that federal regulation governing maximum train speed preempts a negligence claim that a speed under the federal maximum was excessive); *City of New York v. FCC*, 486 U.S. 57, 66–67 (1988) (holding that FCC regulation establishing technical standards to govern the quality of cable television signals preempts more stringent state regulation); *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 170 (1982) (holding that Federal Home Loan Bank Board's regulation permitting federally chartered savings and loan associations to exercise due-on-sale clause of mortgages preempts contrary state common law rule).

[4] *See Watters v. Wachovia Bank, N.A.*, 127 S.Ct. 1559, 1583 n.21 (2007) (Stevens, J., dissenting) (collecting statutes). Such authority should not be implied from a general grant of rulemaking authority. *See Gonzales v. Oregon*, 126 S.Ct. 904, 919 (2006) (noting that a delegation of authority to an agency to promulgate "standards" ordinarily does not "include the authority to decide the pre-emptive scope of the federal statute"); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 766-69 (2008).

the deference described in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

In *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996), the Court considered the effect of an express preemption clause in the Medical Device Amendments to the FDCA. This clause, which applies only to the regulation of medical devices, includes an unusual provision delegating authority to the FDA to "exempt" particular state requirements from preemption. 21 U.S.C. §§ 360k(a), (b) (2000). The Court did not regard this partial delegation of authority to the FDA to mean that courts must defer to any reasonable agency interpretation of the express preemption statute, as would be required by *Chevron*. To the contrary, the Court independently interpreted the ambiguities in the statute, in particular, the uncertainty about the meaning of "requirement." *Medtronic*, 518 U.S. at 486-91. Only after extensive consideration of the interpretative issues did the Court turn to the FDA's views. The Court cited a number of factors that caused it to give those views weight. *Id.* at 496. But the Court did not apply the *Chevron* framework. Instead, it said only that its conclusion was "substantially informed" by the FDA's view about preemption. *Id.* at 495.

The next significant decision to consider agency views on preemption was *Geier v. Am. Honda Motor Co.,* 529 U.S. 861 (2000). The Court held that preemption of state tort liability was required to avoid frustrating a regulation promulgated by the National Highway Traffic Safety Administration calling for a phase-in of passive restraint systems. The Court was careful, however, not to suggest that defer-

ence was required based either on the delegation of power to the agency or the agency's general expertise in matters of auto safety regulation. Instead, the Court concluded only that the agency's views about the impact of state tort law on its regulation were entitled to "some weight" in the circumstances of that controversy. 529 U.S. at 883. The dissenting opinion in *Geier* questioned whether any weight at all should be accorded to the agency's view, given that the States had not been given an opportunity to participate in the development of the agency's opinion. *See id.* at 911-12 (Stevens, J., dissenting).

More recently, in *Watters v. Wachovia Bank, N.A.*, 127 S.Ct. 1559 (2007), the Court reviewed a lower-court judgment that relied on *Chevron* in holding state authority over operating subsidiaries of national banks preempted. The Court affirmed, but the majority found no need to reach the question whether *Chevron* or any other standard of deference was appropriate, since in the majority's view preemption was compelled by the National Banking Act itself. The dissenting opinion did consider what weight should be given to agency views about preemption. *See id.* at 1584 (Stevens, J., joined by Roberts, C.J. and Scalia, J.). The dissenters acknowledged that "expert agency opinions as to which state laws conflict with a federal statute may be entitled to 'some weight,' especially when 'the subject matter is technical' and 'the relevant history and background are complex and extensive.'" *Id.* (quoting *Geier*, 529 U.S. at 883). But the dissenters expressly rejected *Chevron* deference, noting that this would too "easily disrupt the federal-state balance," that agencies are not well designed to represent the interests of States, and that agencies are unlikely to show sufficient respect for state sovereignty. The majority did not

take issue with this analysis, noting only that the question was "academic" given its conclusion that preemption was required by the statute itself. *Id.*

Most recently, the Court again adverted to agency views about preemption in *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008). As in *Watters*, the Court agreed with the agency that preemption was warranted, but also as in *Watters*, the Court "found it unnecessary to rely upon that agency view" because "the statute itself speaks clearly to the point at issue." *Id.* at 1009. A dissenting opinion briefly discussed the agency's recently-adopted view favoring preemption. *See id.* at 1016 n.8 (Ginsburg, J. dissenting). The dissent noted that this view had been advanced only in an *amicus* brief and, as such, was entitled to "at most" the deference afforded under *Skidmore.* Because the agency had changed its position, the dissent thought that view was entitled to little weight. The majority responded that *if* the agency view were relevant, "mere *Skidmore* deference would seemingly be at issue." *Id.* at 1009. Like the dissent, the majority agreed that, in that hypothetical event, only "reduced" deference would be owed the agency given its change in position. *Id.*

Overall, the Court has approached the question of what, if any, deference is owed to agency views about preemption with appropriate caution. No Justice has endorsed the proposition that agency views about preemption are entitled to *Chevron* deference, even if the preconditions for affording that deference are otherwise satisfied. *See United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001) (holding that agency views are entitled to *Chevron* deference only if the agency has been delegated authority to act with the force of law and the interpretation has been prom-

ulgated in an exercise of that authority). The discussions of agency views about preemption in the opinions are more consistent with the standard of review prescribed in *Skidmore*. Yet even here, it is noteworthy that no Justice has forthrightly endorsed the application of the *Skidmore* standard in this context.

The best generalization about the state of the law might be that the Court has acknowledged that agencies can lend assistance to courts in resolving preemption questions, primarily by making informed findings of legislative fact about the impact of diverse state requirements on the implementation of a federal regulatory scheme. Taken as a whole, however, the collective pronouncements of the Court do not support affording any deference to agencies on the ultimate legal question whether preemption of state law is warranted. The Court has "assume[d] (without deciding) that [this] question must always be decided *de novo* by the courts." *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 744 (1996).

II. THE SUPREMACY CLAUSE CONFERS AUTHORITY ON COURTS, NOT AGENCIES, TO RESOLVE PREEMPTION QUESTIONS

To determine the appropriate role of administrative agencies in resolving questions of preemption it is necessary to begin with the source of authority for federal displacement of state authority. This Court has repeatedly identified the Supremacy Clause as the source of federal authority to preempt state law.[5]

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[5] *See, e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 540–41 (2001) (identifying the Supremacy Clause as the "relatively clear and simple mandate" that allows Congress to "pre-empt[]

The text and drafting history of the Supremacy Clause, in turn, strongly suggest that the judiciary is the institution which is to make such determinations.

A. Preemption Questions Are to Be Resolved by "The Judges in Every State"

As a general matter, the Constitution is addressed to all government actors. Perhaps most notably, the Oath Clause requires that an oath or affirmation supporting the Constitution be administered to all legislative, executive, and judicial officers "both of the United States and of the several States." U.S. Const. art. VI, cl. 3. The Supremacy Clause is at once consistent with this generalization, and yet also includes an exception to it. The Supremacy Clause reads in its totality:

> 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.

U.S. Const. art. VI, cl. 2. (emphasis added).

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state action in a particular area"); *Nw. Cent. Pipeline Corp. v. State Corp. Comm'n*, 489 U.S. 493, 509 (1989) (referring to Congress's "power under the Supremacy Clause . . . to pre-empt state law"); *de la Cuesta*, 458 U.S. at 152 (declaring that the "pre-emption doctrine . . . has its roots in the Supremacy Clause"); *Morris v. Jones*, 329 U.S. 545, 553 (1947) (stating that when state law "collides with the federal Constitution or an Act of Congress . . . the action of a State under its police power must give way by virtue of the Supremacy Clause").

The first part of the Supremacy Clause, up to the second semi-colon, clearly applies to all government actors. The Constitution, Laws, and Treaties of the United States must be regarded as the "supreme Law of the Land" by all governmental officers, state and federal. After the second semi-colon, however, the Clause is addressed to one branch of government only: the judiciary. The Clause says that "the Judges in every State" shall be bound by authoritative federal law, any provision of state law to the contrary notwithstanding. Note that the Constitution speaks of "the Judges in every State" not merely of "state judges." This was undoubtedly deliberate.[6] As is well known, the Framers left the decision whether to create lower federal courts to future Congresses to make.[7] The phrase, "the Judges in every State" appears to have been drafted to include all judges, state and potentially federal, without regard to where those judges might serve.[8] In other words, the Supremacy Clause specifically singles out the judiciary as an institution, and sets forth a particular rule of decision it is to apply in sorting out competing claims about the application of federal law versus state law.

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[6] For the drafting history of this phrase, *see* FORREST MCDONALD, NOVUS ORDO SECLORUM: THE INTELLECTUAL ORIGINS OF THE CONSTITUTION 255-56 (1985).

[7] *See* 1 MAX FARRAND, THE RECORDS OF THE FEDERAL CONVENTION 104-05, 119, 124-25 (1911).

[8] Several federal courts, including this Court, sit in Washington, D.C. But their judgments arise out of events, and apply to parties, "in every State." The phrase "in every State" should be taken to mean "throughout the United States." Even if the phrase refers only to state court judges, the Supremacy Clause still represents a considered choice by the framers that the judiciary is the appropriate institution to resolve conflicts between federal and state law.

The inference about institutional roles that can be drawn from the text of the Supremacy Clause is powerfully reinforced by evidence of the original understanding of that Clause and its place in the constitutional order. As multiple commentators have carefully documented, the Constitutional Convention had before it three potential mechanisms for assuring that federal law would prevail in the face of opposition grounded in state law: (1) the use of coercive force against defiant states, (2) James Madison's proposal that Congress be given an unrestricted power to "negative" any state law by federal legislation, or (3) the use of the courts to resolve competing claims of federal and state law.[9] Each option corresponded to a particular institutional choice. Force would be deployed by the Executive; the "negative" by the Legislature; court judgments by the Judiciary. The Convention rejected the first two mechanisms in favor of the third or judicial option. The provision that embodied this important decision was the Supremacy Clause.

The choice made by the framers to entrust the resolution of federal-state conflicts to the courts should not be lightly set aside. Of the various institutions familiar to the framers, they concluded that the courts were best situated to mediate between the claims of the national government and the States.

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[9] *See* JACK N. RAKOVE, ORIGINAL MEANINGS: POLITICS AND IDEAS IN THE MAKING OF THE CONSTITUTION 171–72 (1996); Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1348–72 (2001); S. Candice Hoke, *Transcending Conventional Supremacy: A Reconstruction of the Supremacy Clause*, 24 CONN. L. REV. 829, 856–75 (1992); James S. Liebman & William F. Ryan, *"Some Effectual Power": The Quantity and Quality of Decisionmaking Required of Article III Courts*, 98 COLUM. L. REV. 696, 709–13 (1998).

Modern administrative agencies were unknown to them, and it is impossible to say what they would have thought of relying on federal agencies to make these decisions. We do know that they were willing to trust the courts to make these decisions. This is not some disembodied "original intent." The choice is fully reflected in the language of the Supremacy Clause, with its specific admonition to "the Judges in every State." That judgment is entitled to the greatest respect.

B. Only Agency Action with the Force of Law Can Preempt

The Supremacy Clause contains within it a second limitation relevant to determining the proper role of agencies in preemption controversies. The Clause makes federal policy dominant only insofar as there is some perceived incompatibility between state law and "[t]his Constitution," "the Laws of the United States which shall be made in Pursuance thereof," or federal treaties made before or after the ratification of the Constitution. Obviously, federal agencies cannot enact constitutional provisions or make treaties. The question, therefore, is whether they can promulgate edicts that qualify under the phrase "Laws of the United States which shall be made in Pursuance [of the Constitution]." The initial impulse is to say "Laws" here must refer to federal statutes—duly enacted and constitutionally valid statutes (those "made in Pursuance of" the Constitution). As one scholar has pointed out, all three forms of federal action singled out as "the supreme Law of the Land" entail a high degree of concurrence by representative institutions. In particular, the concurrence of the Senate (which was thought to represent the interests of the small States) appears to be required for each

form of "supreme" lawmaking.[10] Action by federal administrative agencies would seem not to meet this requirement. This Court has concluded that "[t]he phrase 'Laws of the United States' encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization."[11] But the reasoning that would support this conclusion has not been spelled out.

The first point to note is that the meaning of the phrase "Laws of the United States" is more uncertain than first appears. The word "Laws" appears twice in the Supremacy Clause, once in the phrase "Laws of the United States" and then again in the admonition that federal supremacy is to be respected by the judges in every state, "any Thing in the Constitution or *Laws* of any State to the Contrary notwithstanding." One could argue that this second reference to "Laws" must also refer to statutes, namely, state statutes. But notice the consequence of this reading: state common law, the most complete body of legal regulation in effect when the Constitution was adopted, might be insulated from preemption under the Supremacy Clause. Thus, if "Laws" in the second appearance of the word were limited to statutes, the effect would be profoundly dysfunctional. To avoid this dysfunction, and the awkwardness of interpreting the same word to mean different things in the same Clause, "Laws of the United States" should also be construed to include more than just legislation enacted by Congress.

Other structural arguments enter into the picture here too. The meaning of "Laws" in the Supremacy

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[10] *See* Clark, *supra*, 79 TEX. L. REV. at 1355–67.

[11] *City of New York*, 486 U.S. at 63.

Clause should be harmonized with the same word in virtually the same phrase in Article III of the Constitution.[12] In that context, it is well established that "Laws of the United States" include not just federal statutes but also decisional rules adopted by courts as a matter of federal law.[13] This suggests that "Laws of the United States" are not limited to federal statutes, but include other rules of decision that have the force and effect of binding federal law, such as federal common law.[14] If federal decisional rules reached by courts can have preemptive effect as "Laws of the United States," it is not clear why rules adopted by federal agencies cannot—in some circumstances at least—be regarded as "Laws of the United States" for Supremacy Clause purposes.

Similarly, consider the appearance of the word "Laws" in the provision of Article II of the Constitution admonishing the President to "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3. We could again insist that this refers only to statutes enacted by Congress. But surely the Presi-

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[12] U.S. Const. art. III, § 2 ("The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, *the Laws of the United States*, and Treaties made, or which shall be made, under their Authority") (emphasis added). *See* Akhil Reed Amar, *Intratextualism*, 112 HARV. L. REV. 747, 766 (1999).

[13] *See Illinois v. City of Milwaukee*, 406 U.S. 91, 99–100 (1972) (holding that "laws of the United States" for purposes of arising under jurisdiction includes federal common law); *see also Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78–80 (1938) (holding that "law" as used in Rules of Decision Act includes state common law).

[14] *See City of Milwaukee v. Illinois*, 451 U.S. 304, 312–14 (1981). Federal judicial judgments have been held to be included within the scope of the Supremacy Clause. *Chesapeake & Ohio Ry. Co. v. Martin*, 283 U.S. 209, 220–21 (1931).

dent was also expected to see that judicial judgments are faithfully executed, including those that rest on common law. And it is settled that both subordinate executive branch agencies and the President himself must follow duly promulgated agency regulations unless and until they are rescinded.[15] If agency-made "law" is included in the "Laws" that the President must faithfully execute, why should it not also be included in the "Laws" referenced in the Supremacy Clause?

To be sure, the word "Laws" cannot be stretched beyond all recognition. Laws must refer, at a minimum, to explicit or implicit rules that bind the future exercise of governmental authority. Thus, for example, a sense of the Senate resolution or a dictum in an opinion of a court should not be regarded as "Laws" for Supremacy Clause purposes. In the agency context, only agency action that has the force of law should be regarded as providing a predicate for preemption. Legislative regulations and self-executing agency orders have this quality; policy statements and interpretative regulations do not.

It is also necessary to demonstrate that agency action has been adopted "in Pursuance of" the Constitution. Here, the Necessary and Proper Clause provides appropriate guidance. *See* U.S. Const. art I, § 8, cl. 17. If Congress has delegated authority to an agency to act with the force of law, and an agency has fulfilled the conditions for exercising that delegated power, then it is possible to speak of the resulting directive as being one that has been made "in Pursuance of" the Constitution, to wit, in pursuance

[15] *See United States v. Nixon*, 418 U.S. 683, 696 (1974).

of a legislative delegation of lawmaking authority permitted by the Necessary and Proper Clause.

Together, these considerations carry with them a significant limitation on the *type* of agency pronouncement that can qualify as a source of preemption. Of the various types of action agencies can take, only agency action based on a delegation of authority from Congress and having the force of law can qualify as a source of preemption consistent with the language of the Supremacy Clause. Legislative regulations satisfy both conditions implied by the Clause for identifying the type of agency action that can serve as a source of preemption. Such regulations take the form and effect of a statute, and they are issued pursuant to a delegation of authority from Congress to act with the force of law.[16] Agency orders issued pursuant to an adjudication that have self-executing legal force also qualify as having the force of law. Other types of agency action, such as policy statements, interpretative rules, opinion letters, and discussions in preambles, fail to meet either or both of the conditions imposed by the Clause.

Limiting agency action that can serve as the source of preemption to that which has the force of law has other positive consequences. Under the Administrative Procedure Act (APA), the issuance of legislative regulations generally requires that the agency

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[16] *See, e.g.*, *Am. Postal Workers Union, AFL-CIO v. U.S. Postal Serv.*, 707 F.2d 548, 558 (D.C. Cir. 1983) ("A rule can be legislative only if Congress has delegated legislative power to the agency and if the agency intended to use that power in promulgating the rule at issue."). *See Mead*, 533 U.S. at 226–27; *see also Gonzales v. Oregon*, 546 U.S. at 255–56; *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980–81 (2005).

comply with notice and comment procedures.[17] This creates an opportunity for States and other interested parties to express their views before potentially preemptive regulations are adopted. Similarly, agency adjudications that lead to binding orders are subject to significant hearing requirements, either under the APA or due process decisional law.[18] In addition, agency action having the force of law, with rare exceptions, is subject to judicial review, which helps insure that agencies act within the bounds of their legal authority. Limiting the sources of agency preemption to action with the force of law thus helps to insure that those entities most affected by a decision to displace state law have a voice in the matter.

Modern administrative law norms also require that agencies disclose relevant data and provide a reasoned response to material objections raised in the rulemaking process.[19] These disclosure and reason-giving requirements can help supply information that bears on the choice between uniform federal rules or diverse state rules. Accordingly, limiting agency action that can be the source of preemption to legislative rules would also help generate more information and analysis that bears on the pragmatic issues implicated in any decision to displace state law.

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[17] 5 U.S.C. §§ 553(b), (c) (2000); *cf.* 5 U.S.C. § 553(a)(2) (2000); *Mead*, 533 U.S. at 244 (Scalia, J., dissenting).

[18] *See* 5 U.S.C. §§ 556, 557 (2000); *Mathews v. Eldridge*, 424 U.S. 319 (1976).

[19] *See, e.g.*, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–44 (1983).

III. CONSIDERATIONS OF COMPARATIVE ADVANTAGE REINFORCE THE CONCLUSION THAT THE JUDICIARY IS THE PROPER INSTITUTION FOR RESOLVING PREEMPTION QUESTIONS

The judiciary is also the preferred institution for resolving questions of preemption when broader considerations of comparative institutional advantage are taken into account.

A. Preemption Entails the Application of Law Developed by Courts

Given its origins in the Supremacy Clause, it is not surprising that the legal doctrine governing the decision to displace state law through preemption has been developed exclusively by courts, and in particular by this Court. This carefully evolved doctrine is trans-substantive, in the sense that it applies across all fields of regulation. Administrative agencies have played no role in the development of preemption doctrine. When agencies have offered their views about the desirability or need for preemption, they have typically framed their analysis in terms of the categories and precedents developed by the courts.[20] In other words, agencies have justified their support (or opposition) to preemption largely in terms of their reading of judicial opinions, a source of authority that agencies have no special insights in interpreting, and which the judiciary is presumably in a better position to explicate.

In addition, the decision to displace state law presents a variety of concerns that point toward the need

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[20] *See* Nina A. Mendelson, Chevron *and Preemption*, 102 MICH. L. REV. 737, 784-86 (2004).

for a general jurisprudence of preemption which can be developed and applied in a uniform fashion.[21] Only the courts, and in particular this Court—which has the ability to review questions of preemption that arise both from federal and state courts—can serve the function of reviewing preemption questions in a manner that maintains a unified jurisprudence of preemption sensitive to the many systemic values at stake.

B. Preemption Implicates Considerations of Federalism

The decision to displace state law through preemption also implicates important questions of federalism. *See, e.g.*, *Medtronic*, 518 U.S. at 488 (describing preemption of state common law remedies as a "serious intrusion into state sovereignty"). Indeed, from the perspective of the States, there is little difference between a judgment that state law is unconstitutional, and a judgment that state law is preempted. Both types of judgments nullify otherwise duly enacted state statutes and common law rules of decision. In so doing, both types of judgments subtract from the power the States otherwise enjoy as sovereign entities.[22]

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[21] *See* Merrill, *supra*, NW. U. L. REV. at 947-51.

[22] To be sure, preemption decisions can be overridden by Congress. But mobilizing Congress to overrule preemption decisions is difficult, and has rarely been successful. *See* Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 HARV. L. REV. 1604, 1613-14 (2007). Moreover, some constitutional judgments—those based on the dormant aspect of the Commerce Clause—are also subject to revision by Congress, further revealing the close connection between preemption and constitutional invalidation.

Part of our received tradition is the understanding that the judiciary has unique competence to resolve questions of constitutional federalism. Thus, for example, this Court has declined to adopt interpretations of statutes that raise questions of constitutional federalism that otherwise can be avoided, *see, e.g.*, *Gregory v. Ashcroft*, 501 U.S. 452 (1991), and has declined to defer to agency decisions that raise questions of constitutional federalism that can be avoided. *See, e.g., Gonzales v. Oregon*, 126 S.Ct. at 925; *Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*, 531 U.S. 159, 172-73 (2000). The decision to displace state law through preemption should be informed by an understanding of which areas of regulation have been delegated to the federal government, which have traditionally been committed to the States, and when constitutional sensitivities would be irritated either by a determination of concurrent authority or of exclusive federal competence.[23] Agencies are specialized institutions, intensely focused on the details of the particular statutory regimes they are charged with administering. By design and tradition, they are not expected to ponder larger structural issues such as the relative balance of authority between the federal and state governments, the importance of preserving state autonomy, the value of allowing policy to vary in accordance with local conditions, or the systemic advantages of permitting state experimentation with divergent approaches to social problems. *See Gregory v. Ashcroft*, 501 U.S. at 458-59 (summarizing the systemic benefits of federalism).

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[23] *See generally* Brief of *Amicus Curiae* Constitutional and Administrative Law Scholars in Support of Respondents, *Altria Group, Inc. v. Good*, No. 07-562.

C. Preemption Implicates the Scope of Agency Power

Determining whether federal law ousts state law also implicates the scope of agency authority. *See Louisiana Public Service Comm'n v. FCC*, 476 U.S. 355, 374-75 (1986) ("An agency may not confer power upon itself. To permit an agency to expand its power in the face of a congressional limitation on its jurisdiction would be to grant to the agency the power to override Congress. This we are both unwilling and unable to do."). There are a variety of reasons why agencies are not the best monitors of the scope of their own authority. Agencies may at times engage in empire-building, or may resent implicit competition from other sources of regulatory authority like States. Analysts have long observed that agencies, particularly ones devoted to regulation of a single industry, can become too closely identified with the interests of the industry they are supposed to regulate.[24]

Congress has provided for judicial review of agency action in significant part to assure that agencies stay within the bounds of their delegated authority. This Court has been reluctant to carve out any general exception from *Chevron* for agency interpretations that transgress the bounds of agency authority, presumably because of the difficulty of distinguishing

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[24] *See, e.g.*, MARVER H. BERNSTEIN, REGULATING BUSINESS BY INDEPENDENT COMMISSION (1955); George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT SCI. 3 (1971); Samuel P. Huntington, *The Marasmus of the ICC: The Commission, the Railroads, and the Public Interest*, 62 YALE L.J. 171 (1953); *see generally* Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L REV. 1 (1998) (providing an overview of theories and empirical studies).

between "jurisdictional" and "non-jurisdictional" decisions. *Compare Mississippi Power & Light Co.* v. *Mississippi ex rel. Moore*, 487 U.S. 354, 381 (1988) (Scalia, J., concurring in judgment) *with id.* at 386-87 (Brennan, J., dissenting). There is no need in this case, however, to tackle this more general problem. Questions about whether state law should be preempted by federal law are not handicapped by any definitional conundrum similar to the one presented by determining when an agency has acted outside its "jurisdiction." The question whether federal law preempts state law is discrete and readily differentiated from other issues of interpretation. *See* Mendelson, *supra*, 102 MICH. L. REV. at 796 ("Preemption questions are relatively easy to distinguish, *ex ante*, from other categories of interpretative questions, so withdrawing deference on preemption issues would not introduce significant new uncertainty-based costs. . . ."). Consequently, the decision to preempt can be subject to independent judicial review, allowing courts to police the boundaries of agency authority—along this dimension at least—without calling into question the general principle of deference established by *Chevron*.

IV. THE FDA'S VIEWS ON PREEMPTION DO NOT WARRANT DEFERENCE IN THIS CASE

In light of the foregoing considerations, we may summarize the permissible role of administrative agencies in preemption controversies in the form of three principles. (1) Administration action can serve as the basis for a determination of preemption *by a court* only if the administrative action has the force of law, specifically, only if that action takes the form of a binding legislative regulation or a self-executing

adjudicatory order. (2) Administrative agencies can preempt state law on their own authority (and their opinions about the preemptive effect of agency action are entitled to strong deference) only if the power to preempt has been *expressly delegated* to the agency by Congress. (3) Statements of opinion by administrative agencies about the preemptive effect of federal law (assuming the power to preempt has not been expressly delegated to the agency by Congress) are not entitled to judicial deference, although courts can draw upon the assistance of agencies in resolving questions of legislative fact that bear on matters of preemption. Under the foregoing principles, the FDA's views about the preemptive force of the Food Drug and Cosmetic Act in this case are entitled to no deference and should be given minimal weight.

A. The FDA's "Floor and Ceiling" Interpretation of the Act is Entitled to No Deference

A potentially critical issue in this case is whether the FDCA imposes only a floor on information disclosure about FDA-approved drugs, or both a floor and a ceiling. The FDA has advanced the floor-and-ceiling interpretation in its Preemption Preamble, and the Solicitor General, on behalf of the United States, has filed a brief endorsing this interpretation. The FDA's interpretation cannot itself serve as a basis for preemption, and is entitled to no deference.

The FDA's floor-and-ceiling interpretation has never been adopted by the agency in a form that has the force of law, and hence cannot itself serve as a basis for a finding of preemption. The floor-and-ceiling interpretation evidently originated in *amicus curiae* briefs filed by the Justice Department on behalf of

the FDA in products liability cases. *See* 71 Fed. Reg. at 3934. In the Preemption Preamble, the FDA sought to "set forth in some detail the arguments made in those amicus briefs." *Id.* However, no attempt was made to codify the floor-and-ceiling interpretation in the Code of Federal Regulations, as would be appropriate if it had the force of law. *See American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993). And the FDA has not claimed, nor could it, that the floor-and-ceiling interpretation was a necessary step it had to reach in order to issue the revised Labeling Rules, to which they were attached. *Cf. National R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 420 (1992) (agency interpretation entitled to deference if it is a "necessary presupposition" of the decision reached). At most, the floor-and-ceiling interpretation reflects the FDA's legal opinion about the proper conclusion a court should reach about the preemptive effect of its labeling regulations. It was simply that—an agency legal opinion—not agency action having the force of law.

Similarly, no argument has been or could be made that Congress has delegated authority to the FDA to preempt state regulation of drug labeling or state tort law dealing with failure to warn about pharmaceutical hazards. Congress knows how to delegate such authority, as when it delegated authority to the FDA to adjust the scope of preemption related to medical devices. *See* 21 U.S.C. §§ 360k(a), (b) (2000); *Medtronic*, *supra*. The claim of preemption in this case is based solely on implied preemption doctrines, not on delegated authority. It follows that no deference is due to the FDA's opinions about the need for preemption.

Moreover, insofar as the FDA's new theory rests on determinations of legislative fact, it is entitled to little or no weight. This Court has stated that even if administrative views on preemption do not compel deference, they may be entitled to "weight," especially if they illuminate the critical question of how diverse state requirements or standards would affect the federal regulatory regime. *See* Part I, *supra*. The FDA has said virtually nothing about this critical issue, however, and hence its analysis is not entitled to any "weight." Most of the agency's arguments have either been conceptual in nature, or have stressed empirical propositions that are irrelevant to the need for a single federal disclosure standard, as opposed to multiple standards.

The agency's most complete defense of the floor-and-ceiling construction of the Act is set forth in its Preemption Preamble. *See* 71 Fed. Reg. at 3935. The agency's arguments in support of this construction, however, largely reduce to the proposition that the FDA believes it is a better regulator than state courts and juries. Thus, the FDA argued that "[o]verwarning, just like underwarning, can similarly have a negative effect on patient safety and public health," *id.*, and that the FDA has greater expertise than "lay judges and juries." *Id.* Whether or not these claims are correct, they do not illuminate the critical question of whether the very existence of diverse standards would undermine or compromise the federal scheme. Even if Congress agreed with the FDA's assessment of its superior expertise, it does not follow that Congress would want to eliminate all competition among political jurisdictions over disclosure standards, or that it would want to eliminate the traditional source of compensation for persons injured by inadequate warnings. Similarly, the Solicitor

General's brief filed in this Court, while purporting to "articulate[] a more generally applicable rule of decision" than the FDA provided in its Preamble (U.S. Brf. at 27), offers no substantive argument or evidence that would explain why a single federal labeling standard is necessary, or how the existence of multiple labeling standards would frustrate or undermine the federal regulatory scheme.

Moreover, the agency has never solicited public comment on the important factual premises that might support a preemption finding. The lengthy Notice of Proposed Rulemaking (NOPR) that initiated the process of public comment on the revised Labeling Rules provided no clue that the FDA was considering action that would have any preemptive effect. *See Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels*, 65 Fed. Reg. 81082-81124 (2000); *see also* 66 Fed. Reg. 17375 (2001) (extending comment period). Indeed, the NOPR said the "proposed rule does not preempt State law." 65 Fed. Reg. at 81103. Thus, the FDA never put the States and other interested parties on notice that it might endorse a legal theory that would strip the States of significant regulatory authority. Commentators have uniformly agreed that agencies need to provide better notice and hearing opportunities if their findings about the need for federal uniformity are to be taken seriously.[25]

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[25] *See, e.g.*, Mendelson, *supra*, 102 MICH. L. REV. at 777-78; Merrill, *supra*, 102 NW. U. L. REV. at 756-57; 764-65; Sharkey, *supra*, 56 DEPAUL L. REV. at 252-54.

B. The FDA Is Not Entitled to *Auer* Deference for Its Interpretation of the CBE Regulation

The FDA should also be denied any deference under *Auer v. Robbins*, 519 U.S. 452 (1997), for its recent "interpretation" of the CBE regulation that would limit pre-approval changes in drug label warnings to those supported by new data or studies. Preliminarily, we would note that the issue with respect to impossibility is very narrow. Under the Vermont Supreme Court's reading of the CBE regulation, which is consistent with its plain language, a drug manufacturer may change its labeling to strengthen warnings of a specific safety hazard before it obtains FDA approval of the change. Under petitioner's and the FDA's view of the matter, unless the manufacturer can point to new studies or data supporting a strengthened warning, the manufacturer must seek and obtain the FDA's approval before making any change. If the FDA eventually *agrees* with the proposed change, then of course there would be no conflict between federal and state law, and the change could be implemented. So the question boils down to what happens in the interim period between the announcement of a new, strengthened warning requirement as a matter of state law, and the FDA's review of a manufacturer's proposal as to how to comply with that requirement. Can the label be changed until the FDA disapproves it, or does the new label remain in limbo until the FDA approves it?

The question is not only narrow, it may be of only transitory significance. The FDA has published a Notice of Proposed Rulemaking seeking comment on whether it should codify its new restrictive interpretation of the CBE regulation, limiting a manu-

facturer's ability to strengthen label warnings to situations where new data or studies support the heightened warning. *See Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 Fed. Reg. 2848 (2008). If the FDA ultimately decides to promulgate such a regulation, and if this revision is determined to be consistent with the Act and relevant procedural requirements, then the FDA's interpretation could be considered by a court in determining its implications for preemption. As things now stand, however, the rule is only a proposal; it has no legal effect.

All of which highlights why it is inappropriate to defer to the FDA's "interpretation" of the CBE regulation in this case, which would achieve the same result as the proposed regulation but by the shortcut of acting in a fashion that lacks the force of law. For the reasons previously given, agency action can provide the basis for a preemption determination by a court only when the agency acts with the force of law. The FDA (we assume) acted with the force of law when it adopted the CBE regulation. But it has not acted with the force of law in amending that regulation to incorporate the new-data-or-studies limitation—at least not yet. Consequently, to grant *Auer* deference to the FDA's "interpretation" of the CBE regulation as incorporating the new limitation would sanction an end-run around the principle that agency action has potential preemptive force only when it has the force of law.

Similarly, for reasons previously given, courts should give agencies strong deference on questions of preemption only when Congress has *expressly delegated* authority to the agency to preempt state law. Congress has not delegated such authority to

the FDA. Consequently it would be inappropriate to grant *Chevron* or similar strong deference to an FDA determination that the Act preempts state warning requirements pending FDA approval. If an FDA interpretation of the Act as requiring preemption would not garner strong deference, it would be improper to give a similar degree of strong deference to an FDA "interpretation" of a regulation that would yield the same result. This would allow agencies to bootstrap their way to deference by issuing vague regulations, which are then "clarified" by interpretations that would be given strong deference. *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 525 (1994) (Thomas, J., dissenting).

This Court has previously recognized that *Auer* deference should not be used to achieve by indirection results that would not be permitted if pursued by an agency directly. In *Gonzales v. Oregon*, the Court ruled that *Auer* cannot be applied to a regulation that merely "parrots" the language of the statute. 126 S.Ct. at 915-16. The reason is straightforward. If an agency would not be entitled to *Chevron* deference for an interpretation of a statute (because the matter is beyond the scope of the agency's delegated authority), then the agency cannot achieve the same end by issuing a regulation that tracks the statute and then purporting to "interpret" the regulation. For the same fundamental reason, if an agency has not acted in a manner that would justify preemption, and would not be entitled to deference on a question of preemption, it should not be allowed to achieve this impermissible result through the device of an interpretation of a regulation.

CONCLUSION

For the foregoing reasons, the judgment of the Vermont Supreme Court should be affirmed.

Respectfully submitted,

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