

merely asserted, without citing support, that because the September 11th hijackers were Arab Muslims and al Qaeda is led by and largely composed of Arab Muslims, it should therefore “come as no surprise that a legitimate policy . . . [of] arrest[ing] and detain[ing] individuals because of their suspected link to the attacks would produce a disparate, incidental impact on Arab Muslims, even though the purpose of the policy was to target neither Arabs nor Muslims.”⁸² While this explanation may be more likely than intentional discrimination, the Court seemed to base this determination on its own intuition and “common sense” rather than on supporting precedent or legal commentary. Judges should not be making fine-tuned probability determinations when deciding a motion to dismiss, especially when they are relying merely on their own intuitions to make those determinations. The *Iqbal* Court effectively stated that federal courts should dismiss a complaint if the allegations do not “ring true.”⁸³

The *Iqbal* Court did not simply expand *Twombly*’s plausibility standard to all federal cases; it substantially strengthened the standard by adding a probability requirement. Federal courts can now dismiss complaints whenever they think that legal conduct is a more likely explanation for the allegations than is illegal conduct. Such a standard is likely to impose a substantial hurdle on nearly all types of litigation and to provide judges a great deal of discretion to weed out cases before they reach discovery. Plaintiffs will have to plead facts showing why alternative explanations for conduct are not as likely as are their claims — a difficult obstacle at such an early stage of litigation. The decision will be a particularly large obstacle in contexts — such as employment discrimination — in which it is improbable that a plaintiff has concrete evidence of a defendant’s wrongdoing and motivation before discovery. Furthermore, *Iqbal* will weaken the truth-seeking function of litigation; paradoxically, plaintiffs will be unable to use discovery to gain information unless they already have access to sufficient information to satisfy the plausibility standard.

B. Federal Preemption of State Law

Preemption of State Common Law Claims. — If the Supreme Court’s preemption jurisprudence has been confused up to this point,¹ its intersection with judicial treatment of agency statutory interpreta-

⁸² *Iqbal*, 129 S. Ct. at 1951.

⁸³ Adam Liptak, *Case About 9/11 Could Lead to a Broad Shift on Civil Lawsuits*, N.Y. TIMES, July 21, 2009, at A10.

¹ See, e.g., William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1576 (2007) (“[T]he Supreme Court’s preemption case law . . . has accurately been characterized as a ‘muddle.’” (quoting Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 232 (2000))).

tion remains at least as unsettled.² After *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,³ the Court has struggled to resolve a perceived tension between the normative values underlying preemption jurisprudence and the rationales justifying deference to agency interpretations of law. Despite having had opportunities to offer a conclusive statement⁴ and many proposed solutions from commentators,⁵ the Court has proceeded slowly. Last Term, in *Wyeth v. Levine*,⁶ the Court held that the Food and Drug Administration's (FDA) approval of a drug's labeling did not preempt a state law failure-to-warn tort claim against the drug's manufacturer. In doing so, the Court granted no deference to a regulatory preamble issued by the FDA. Instead, the Court adopted an approach that continues to treat preemption questions as a category apart from the general regime of *Chevron* deference. *Wyeth* demonstrates, however, that the Court's perceived need for a distinct approach to agency preemption interpretations is unfounded. Applying the general *Chevron* deference regime would respond to institutional choice concerns counseling deference to agencies on questions of statutory interpretation while still allowing courts to have an effective role in protecting against federalism concerns.

On April 7, 2000, Diana Levine visited a local clinic to receive treatment for a migraine headache and was twice administered the drug Phenergan.⁷ The second time, the clinician administered Phener-

² See, e.g., Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 759 (2008) (“[D]efining the appropriate role of agencies in preemption cases is one of the most vexed issues of public law currently confronting the Supreme Court.”).

³ 467 U.S. 837 (1984).

⁴ See, e.g., *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1009 (2008) (suggesting that, had the Court needed to consult the agency view, “mere *Skidmore* deference would seemingly be at issue”); *Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1572 (2007) (sidestepping the issue of whether to accord *Chevron* deference to a regulation promulgated by the Office of the Comptroller of the Currency interpreting the preemptive effect of the National Bank Act). Whatever level of deference it has claimed to be according, the Court has generally, and particularly in product liability preemption, found its view to be consistent with that of the regulating agency. See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 471 (2008) (noting that, as a descriptive matter, the position the Supreme Court took regarding preemption in each product liability case except one from 1992 to 2008 did demonstrate consistency with that of the federal agency).

⁵ See, e.g., Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737, 742 (2004) (suggesting a regime for preemption that adopts a level of deference to the agency view similar to that granted in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), such that courts enforce the presumption against preemption but may defer to agency interpretations that they find persuasive); Merrill, *supra* note 2, at 775–76 (advocating a “*sui generis*,” *id.* at 775, approach with potentially greater deference when agencies arrive at their positions through consultative procedures such as notice-and-comment rulemaking).

⁶ 129 S. Ct. 1187 (2009).

⁷ *Id.* at 1191.

gan via the IV-push method,⁸ and the drug subsequently entered Levine's artery.⁹ Contact between the extremely corrosive drug and Levine's arterial blood produced gangrene, resulting in Levine losing her hand and then her entire forearm to successive amputations.¹⁰ Levine brought a common law tort suit against Wyeth, Phenergan's manufacturer.¹¹ She asserted that Phenergan's labeling, which warned of the consequences of inadvertently introducing the drug into an artery but did not instruct clinicians to use the safer IV-drip method, was insufficient, and that, given the foreseeable risks, IV-push-administered Phenergan was "not reasonably safe."¹² Wyeth moved for summary judgment, arguing that FDA approval of Phenergan's labeling preempted such tort suits under theories of both field and conflict preemption.¹³ After the trial court rejected this motion, a Vermont state jury found Wyeth negligent, the product defective due to insufficient warnings, and an intervening cause absent between defect and injury.¹⁴ The trial judge rejected Wyeth's motion for judgment as a matter of law, and Wyeth appealed.¹⁵

The Vermont Supreme Court affirmed, holding that Wyeth's ability to strengthen its warning without prior approval obviated any direct conflict between the verdict and the requirements imposed by either the Food, Drug, and Cosmetic Act¹⁶ (FDCA) or the FDA.¹⁷ It also found federal labeling requirements to be a floor, not a ceiling, for the label's content, rendering an obstacle preemption argument unworkable.¹⁸ Chief Justice Reiber dissented, finding compliance with both laws impossible and the jury's verdict, because it contradicted the agency's judgment that IV-push-administered Phenergan was safe and effective, an obstacle to federal purposes and objectives.¹⁹

The Supreme Court granted certiorari and affirmed.²⁰ Writing for the Court, Justice Stevens²¹ held that FDA approval of Phenergan's labeling did not preempt Levine's tort claims. The Court rejected Wyeth's arguments regarding both impossibility preemption and ob-

⁸ Of the three possible methods of administering Phenergan, IV-push presents the greatest risk of inadvertent arterial contact. *See id.* at 1192.

⁹ *Id.* at 1191.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.* at 1191-92.

¹³ *Id.* at 1192. The field preemption argument was abandoned on appeal. *Id.*

¹⁴ *Id.* at 1193.

¹⁵ *Id.*

¹⁶ 21 U.S.C. §§ 301-399a (2006).

¹⁷ *See* *Levine v. Wyeth*, 2006 VT 107, ¶ 23, 183 Vt. 76, 944 A.2d 179.

¹⁸ *See id.* ¶ 28.

¹⁹ *Id.* ¶¶ 54-64 (Reiber, C.J., dissenting).

²⁰ *Wyeth*, 129 S. Ct. at 1204.

²¹ Justice Stevens was joined by Justices Kennedy, Souter, Ginsburg, and Breyer.

stacle preemption, grounding its analysis in two doctrinal “cornerstones”:²² congressional purpose and a federalism-protecting presumption against preemption.²³

With respect to Wyeth’s impossibility preemption theory,²⁴ the Court noted that, while usually a manufacturer may change label content only after FDA approval, a “changes being effected” regulation permitted changes pending FDA approval so long as those changes strengthened or added to the warning or instruction and resulted from “newly acquired information,” including new analyses of old information.²⁵ This regulation would have permitted Wyeth to strengthen the IV-push warning unilaterally,²⁶ in keeping with the “central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.”²⁷ To show impossibility, Wyeth would have had to produce clear evidence that the FDA would have rejected the strengthened warning; the record developed in the lower courts provided no such evidence.²⁸

The Court found Wyeth’s obstacle preemption theory to “rel[y] on an untenable interpretation of congressional intent and an overbroad view of an agency’s power to pre-empt state law.”²⁹ The Court reasoned that Wyeth’s interpretation of the FDCA as establishing both a ceiling and a floor for the content of a drug’s label was in substantial tension with the Act’s perceived primary purpose of consumer protection, its failure to provide federal remedies for consumers,³⁰ and its lack of an express preemption clause despite Congress’s “certain awareness of the prevalence of state tort litigation.”³¹

The Court also rejected Wyeth’s argument for deference to the FDA. It granted no weight to a 2006 FDA regulatory preamble asserting that the FDCA established both a floor and a ceiling for label con-

²² *Wyeth*, 129 S. Ct. at 1194.

²³ *Id.* at 1194–95. The Court applied a presumption against preemption despite a long history of federal regulation in the field, *see id.* at 1195, and despite the dissent’s claim that the presumption had not been applied previously to implied conflict preemption, *see id.* at 1228–29, 1229 n.14 (Alito, J., dissenting).

²⁴ Before considering either specific theory, the Court mentioned some relevant points in the history of the FDA’s organic statute. It noted that a 1962 amendment granting the FDA greater regulatory power also included a savings clause limiting preemption to “direct and positive conflict,” *id.* at 1195–96 (majority opinion) (quoting Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (codified at 21 U.S.C. § 321 (2006))), and that although Congress enacted an express preemption clause for medical devices in 1976, *see* 21 U.S.C. § 360k, it failed to do so for prescription drugs, *Wyeth*, 129 S. Ct. at 1196.

²⁵ *Wyeth*, 129 S. Ct. at 1196 (citing 21 C.F.R. § 314.70(e)(6)(iii) (2009)).

²⁶ *Id.* at 1197.

²⁷ *Id.* at 1197–98.

²⁸ *Id.* at 1198–99.

²⁹ *Id.* at 1199.

³⁰ *Id.* at 1199–1200.

³¹ *Id.* at 1200.

tent and that state tort actions threatened the FDA's intended role in this system.³² The Court noted that, while in *Geier v. American Honda Motor Co.*,³³ it had recognized that an agency regulation with the force of law could preempt state law, *Wyeth* involved only an assertion made by an agency without explicit congressional preemption authorization.³⁴ The *Geier* majority had given some weight to the agency view not out of recognition of a special grant of authority to the agency but rather due to agencies' "unique understanding of the statutes they administer," with the ultimate weight accorded depending on the "thoroughness, consistency, and persuasiveness" of the agency's view.³⁵ Focusing on these same factors, the *Wyeth* majority found the FDA's view to merit no deference for three reasons: it resulted from a notice-and-comment process that gave no notice of the preamble's federalism implications, it was at odds with the Court's view of Congress's purpose, and it reversed the agency's previous position without explanation.³⁶

Justice Breyer concurred. He noted that this case did not present the Court with an opportunity to analyze the preemptive effect of a regulation bearing the force of law, but suggested that in an appropriate case the FDA could make a determination that a state requirement was a hindrance, situate that determination in a properly promulgated rule, and perhaps obtain deference.³⁷

Justice Thomas concurred in the judgment. While agreeing that impossibility preemption did not apply, he refused to join what he perceived to be the Court's endorsement of expansive and strongly purposivist implied obstacle preemption.³⁸ For Justice Thomas, federalism-based concerns and the Supremacy Clause's text required granting preemptive effect only to laws made pursuant to Congress's enumerated powers and in compliance with "the complex set of procedures that Congress and the President must follow to enact 'Laws of the

³² See *id.* at 1200–01. Among other things, the preamble stated that the "FDA interprets [the FDCA] to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314 & 601). Thus, the FDA "believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law." *Id.* at 3934.

³³ 529 U.S. 861 (2000).

³⁴ *Wyeth*, 129 S. Ct. at 1200–01.

³⁵ *Id.* at 1201. The "unique understanding" rationale was heightened in *Geier* due to the complex nature of the subject matter and regulatory history of the statute in that case. *Id.*

³⁶ See *id.* The Court also gave no deference to the government's amicus brief because it represented a dramatic change from the FDA's prior interpretation. *Id.* at 1203 n.13.

³⁷ *Id.* at 1204 (Breyer, J., concurring).

³⁸ See *id.* at 1204–05 (Thomas, J., concurring in the judgment).

United States,”³⁹ which would encompass statutory text but not “[c]ongressional and agency musings.”⁴⁰ Permitting consultation of sources beyond the text would create the risk of “freeranging speculation” about statutory purpose⁴¹ and the displacement of clear statutory text in favor of systematically overexpansive views of intended purpose.⁴² Finally, Justice Thomas disputed the need to recognize a presumption against preemption given the statutory text’s lack of preemptive effect⁴³ and the absence of impossibility preemption.⁴⁴

Justice Alito dissented.⁴⁵ He claimed that the resolution of this case depended not on whether a duty of adequate warning existed, but on who should resolve disputes over adequacy or safety, with state common law tort suits serving as a “frontal assault” on an FDA-centered regime.⁴⁶ The dissent disagreed with the majority as a factual matter on the degree to which the FDA had previously considered the IV-push issue.⁴⁷ In addition, Justice Alito first interpreted *Geier* as rejecting the need for notice and comment in order for agency action to have preemptive effect.⁴⁸ Second, he asserted that the FDA passed *Geier*’s force-of-law test because, even if the preamble in question did not have this force, the decision to approve Phenergan’s labeling certainly did.⁴⁹ Finally, the dissent noted that the *Geier* majority had not expressly invoked any presumption against preemption and had, overstrident dissent, given some weight to an agency amicus brief, an approach the *Wyeth* dissenters would have continued to follow regardless of any change in agency position highlighted by the majority.⁵⁰

Wyeth thus represents another in a line of cases at the intersection of administrative law and preemption jurisprudence, a field left largely unsettled after *Chevron*. The unanswered questions at this juncture

³⁹ *Id.* at 1206–07.

⁴⁰ *Id.* at 1207–08.

⁴¹ *See id.* at 1212.

⁴² *Id.* at 1214–15. Justice Thomas additionally criticized the significance the majority gave to congressional inaction in this case. *Id.* at 1216–17.

⁴³ *See id.* at 1208 n.2.

⁴⁴ *See id.* at 1208–10. Justice Thomas based this conclusion on *Wyeth*’s ability to strengthen the warning without prior FDA approval and the lack of an absolute right to market FDA-approved drugs. *Id.* Justice Thomas did, however, note that the currently demanding impossibility preemption standard may reflect the corresponding expansiveness of the “purposes and objectives” preemption doctrine. *Id.* at 1209.

⁴⁵ Justice Alito was joined by Chief Justice Roberts and Justice Scalia.

⁴⁶ *Wyeth*, 129 S. Ct. at 1218 (Alito, J., dissenting). The regime, Justice Alito noted, involved both rigorous prescreening by manufacturers and a continuing obligation on their part to report to the FDA. *Id.* at 1219.

⁴⁷ *See id.* at 1222–25. The dissent also suggested that *Geier* had established that the degree of intrusion was irrelevant to the preemption inquiry. *Id.* at 1227.

⁴⁸ *Id.* at 1228.

⁴⁹ *Id.* (noting FDA authority to make law by administrative adjudication).

⁵⁰ *Id.* at 1228–29.

are, first, whether courts should defer to agency preemption determinations and, second, if they do, what level of deference should be accorded in light of the preemption doctrine's countervailing federalism concerns. Even with *Wyeth*, the Court has not conclusively resolved these questions, although it continued its practice of withholding preemption determinations from the general *Chevron* regime. This approach creates a tension between the Court's treatment of agency views and the supposed balance of congressional purpose and federalism concerns in preemption cases. However, this unique approach for preemption is unnecessary. Rather, the general approach to deference after *United States v. Mead Corp.*⁵¹ would permit the same result in this case and better allow courts to recognize institutional choice concerns that justify deference to agency statutory interpretation while still protecting the overall federal balance of power.

The foundation of the Court's preemption jurisprudence rests in the Constitution's clear declaration that all "Laws of the United States" are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."⁵² Given Congress's clear power to displace state law in the exercise of its constitutional authority, "preemption 'is basically [a question] of congressional intent.'"⁵³ Courts have developed a number of doctrinal methods to ascertain whether the required intent exists. Preemption may be either express — grounded directly in statutory language⁵⁴ — or implied — based on the "physical impossibility" of complying with both state and federal law,⁵⁵ on state law constituting "an obstacle" to the federal law's purpose,⁵⁶ or on evidence of congressional "intent to occupy a given field."⁵⁷ In addition to multiple theories of intent, however, the Court has also applied, with varying degrees of weight, a "presumption against preemption"⁵⁸ — in the express and now the implied preemption context — to balance recognition of Congress's abil-

⁵¹ 533 U.S. 218 (2001).

⁵² U.S. CONST. art. VI, cl. 2.

⁵³ Christopher H. Schroeder, *Supreme Court Preemption Doctrine*, in PREEMPTION CHOICE 119, 120 (William W. Buzbee ed., 2009) (alteration in original) (quoting *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996)).

⁵⁴ See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517–18 (1992).

⁵⁵ *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143 (1963).

⁵⁶ *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

⁵⁷ *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984).

⁵⁸ See, e.g., *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (describing the presumption as "the assumption that the historic police powers of the States [are] not to be superseded by [a federal statute] unless that was the clear and manifest purpose of Congress"). Rationales for the presumption include presumed congressional intent or, more plausibly, use of it as either a de-liberation-forcing mechanism or simply a "substantive bias in favor of state autonomy." See Robert R.M. Verchick & Nina Mendelson, *Preemption and Theories of Federalism*, in PREEMPTION CHOICE, *supra* note 53, at 13, 23.

ity to preempt with a desire to protect and enforce the values of the federal system.⁵⁹

Independently, in the context of agency statutory interpretation, *Chevron* and the cases following it provoked an enduring change in how courts and agencies divide interpretive authority over ambiguous statutes. The *Chevron* Court cited a variety of rationales for deferring to agencies' interpretations of law, among them the agencies' presumed superior expertise and accountability with respect to the statutes they administer.⁶⁰ Agencies are the primary interpreters in this new regime, with courts in the more limited secondary role of determining, first, whether the provision interpreted is ambiguous and, second, whether the agency's interpretation is "permissible."⁶¹ *Mead* limited the scope of application of this two-step deference by adding an initial determination: whether Congress actually intended to delegate interpretive authority to the agency, with such a delegation likely when "Congress delegated authority to the agency generally to make rules carrying the force of law, and . . . the agency interpretation claiming deference was promulgated in the exercise of that authority."⁶² At the same time, however, *Mead* clearly grounded the decision to defer in a presumption about congressional intent: in cases of statutory ambiguity, agencies are Congress's chosen interpreters.⁶³

The difficulty at the intersection of these bodies of law is reconciling *Chevron* deference with the nondeferential balance set in preemption jurisprudence, in which the courts both determine congressional intent and weigh it against the presumption against preemption. The primary difficulty with applying the *Chevron* framework to agency statutory interpretations regarding preemption is a concern about agencies' ability to handle the second component of the preemption inquiry: giving appropriate weight to federalism considerations. The FDA's attempted "backdoor federalization"⁶⁴ in *Wyeth* — its attempt

⁵⁹ Cf., e.g., *Wyeth*, 129 S. Ct. at 1205 (Thomas, J., concurring in the judgment) (noting that the federal system protects against tyranny, allows for laws more adapted to local needs, and provides increased opportunity for civic participation). The Court's commitment to protecting federalism in its preemption jurisprudence via the consistent application of the presumption against preemption has not gone unquestioned. 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, 1604 (2007) (collecting sources).

⁶⁰ See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 865 (1984).

⁶¹ See *id.* at 842–43.

⁶² *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001) (suggesting the "power to engage in adjudication or notice-and-comment rulemaking" as itself a good proxy for the existence of force-of-law authority, *id.* at 227).

⁶³ See *id.* at 229.

⁶⁴ Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 228 (2007); see also Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 232–33 (noting views that

to establish preemption using a regulatory preamble promulgated through a process that offered no meaningful opportunity for comment⁶⁵ — seems substantially to justify this concern that agencies may be unwilling or unable to perform the federalism analysis effectively. Further, the Court's reasons for refusing to grant *Chevron* deference in *Wyeth* as a result of this "backdoor" process are also consistent with another concern thought by some to support reduced deference in the preemption interpretation context: agencies might attempt to expand their own jurisdictions at the expense of state autonomy.⁶⁶

However, rather than revealing the need for preemption questions to be handled outside the ordinary agency deference regime, *Wyeth* demonstrates that the *Chevron/Mead* regime alone could have curbed even the supposed dangers of agency preemption interpretations. Applying *Mead* to determine whether Congress intended to delegate interpretive authority to the FDA in this context would almost certainly have resulted in a finding of no or reduced deference. Although Congress had "delegated authority to the agency generally to make rules carrying the force of law,"⁶⁷ the regulatory preamble was not "promulgated in the exercise of that authority."⁶⁸ In this situation, therefore, *Mead* counsels against a grant of full deference to the agency interpretation and in favor of either *Skidmore v. Swift & Co.*⁶⁹ deference or de novo judicial interpretation. *Mead*'s approach thus would serve perfectly well the gatekeeping role of screening out agency preemption interpretations that ignore congressional limits.⁷⁰ While there is some possibility that agency preemption interpretations may be systematically biased toward expanding their jurisdiction,⁷¹ there is no empirical basis to believe this is the case.⁷²

agencies are ill-suited to resolve questions of "state interests," *id.* at 232, and that they lack expertise on the proper overall state-federal balance); Mendelson, *supra* note 5, at 779–91.

⁶⁵ See *Wyeth*, 129 S. Ct. at 1201–02.

⁶⁶ See Mendelson, *supra* note 5, at 794–97; see also Gersen, *supra* note 64, at 233–34 (noting the alleged dangers associated with an agency interpreting the extent of its own jurisdiction). The stability of precedent-based judicial interpretation has also been cited as a benefit that would be lost under a system of deferring to agency interpretations on preemption questions. See Merrill, *supra* note 2, at 757–58.

⁶⁷ *Mead*, 533 U.S. at 226–27.

⁶⁸ *Id.* at 227.

⁶⁹ 323 U.S. 134 (1944).

⁷⁰ Cf. Lisa Schultz Bressman, *Chevron's Mistake*, 58 DUKE L.J. 549, 557 (2009) (describing *Mead*'s gatekeeping function in the context of general agency delegation questions).

⁷¹ If such bias does exist, it may either be another factor to consider in *Mead*'s analysis of congressional intent to delegate, or justify denying *Chevron* deference altogether even to preemption interpretations that otherwise meet the *Mead* standard.

⁷² See Gersen, *supra* note 64, at 235. At the same time, this possibility of agency bias relates to the long-running discussion over the larger question of whether agencies should receive deference for interpretations of their jurisdictional scope. Compare *Miss. Power & Light Co. v. Mississippi ex rel. Moore*, 487 U.S. 354, 380–82 (1988) (Scalia, J., concurring in the judgment) (terming defer-

Locating preemption questions solidly within the *Chevron/Mead* framework also better accommodates the fact that preemption questions may be even more technical and thus better suited to agency interpretation than are the ordinary gap-filling questions that originally justified *Chevron* deference. Resolving whether preemption was intended or better serves the statutory purpose demands sophisticated knowledge regarding the likely effects of uniform rules as opposed to diversity in a particular regulatory context, as well as a developed fact-finding ability.⁷³ This point is especially true as the Court has shifted from the language-focused express preemption approach of *Cipollone v. Liggett Group, Inc.*⁷⁴ to the implied preemption analysis that has characterized the Court's products liability preemption cases since 1996.⁷⁵ Given the technical burden of implied preemption, the natural conclusion is that an agency administering a statute may be better able to determine the practical effect of a particular preemption decision.⁷⁶

Contrary to the fears of some, use of the *Chevron/Mead* framework could also help ameliorate lingering federalism concerns. First, increased use of notice and comment by agencies to obtain deference would provide at least one means for the federalism implications of a preemption decision to be raised before and considered by the agency.⁷⁷ Second, while federalism-based concerns may remain plausible reasons for courts to play a more active role in the interpretation of preemption questions, these concerns have not been consistently reflected in the Court's preemption jurisprudence.⁷⁸ As in *Wyeth*, a presumption against preemption may be invoked, but the overall pur-

ence in this context to be both necessary and appropriate), *with id.* at 386–88 (Brennan, J., dissenting) (arguing for no deference based on a lack of expertise and a presumed lack of congressional intent to delegate for questions of jurisdictional scope). Indeed, the pattern of preemption agency interpretations is now being discouraged. See Memorandum from the President of the United States to the Heads of Executive Departments and Agencies (May 20, 2009), available at http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption. Some commentators have also suggested that an agency's estimation of its own competence may be inflated. See David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 465 (2008) (arguing that the FDA's preemption argument was based on an unrealistic view of its post-approval monitoring abilities). While an inflated view of its own competence might lead the agency systematically to overvalue the benefits of uniform, federal regulation, it is nonetheless similarly unclear that this phenomenon is an intrinsic source of bias in preemption interpretations.

⁷³ See Merrill, *supra* note 2, at 755–57. The sheer volume of the amicus briefs submitted in *Wyeth* provides some indication of the factfinding burden imposed and the limitations on the ability of the appellate litigation process to bear it.

⁷⁴ 505 U.S. 504 (1992); *see id.* at 517.

⁷⁵ See Keith N. Hylton, *Preemption and Products Liability: A Positive Theory*, 16 SUP. CT. ECON. REV. 205, 208 (2008) (noting a change following *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)).

⁷⁶ See, e.g., Sharkey, *supra* note 4, at 485.

⁷⁷ See Merrill, *supra* note 2, at 757–58.

⁷⁸ See Note, *supra* note 59, at 1604.

posivist bent of the Court's interpretation may not change appreciably. In such a situation, it is not clear that adding a presumption of some indeterminate weight gives voice to any concretely developed federalism concerns.⁷⁹ In contrast, recognizing that agencies are generally the "superior purposivists" as compared to courts, both in determining the purpose at issue and in choosing the appropriate policy to advance it,⁸⁰ the Court, when confronted with a properly promulgated agency decision, would then be forced to make federalism concerns and their underlying normative goals a more explicit part of the decision to displace the agency view.⁸¹ By forcing a separation of the two elements of preemption analysis — the question of congressional preemptive intent and the desire to protect federalism concerns — the Court would better be able to assign each element to the institution best able to determine it. Agencies would resolve technical questions of preemptive intent and courts would be able to defend federalism concerns expressly, thereby balancing the two concerns more effectively than courts can alone through the placement of a thumb of varying weight on the scale of their own purposivist or textual analyses.

Thus, this case demonstrates that, while there are enduring concerns with respect to agency interpretation of preemption questions, the traditional *Chevron/Mead* deference framework can address these concerns, with no need for a singular approach for preemption questions. Bringing the doctrine in this area in line with the overall agency deference approach promises both to take advantage of agency interpretive strengths and to force the Court to articulate the federalism-inspired concerns that may be driving its enduring reluctance to defer.

C. Qualified Immunity

Order of Analysis. — The doctrine of qualified immunity sensibly allows courts to balance citizens' interests in having remedies for violations of constitutional rights with governmental actors' interests in fulfilling their duties without fear of legal challenge.¹ In *Saucier v. Katz*,² following disagreement among the federal circuits as to how to

⁷⁹ Indeed, it is noteworthy that in a case adopting the presumption against preemption in the implied preemption context, the only sustained evocation of the benefits of the federal system came in Justice Thomas's opinion concurring in the judgment. See *Wyeth*, 129 S. Ct. at 1205 (Thomas, J., concurring in the judgment).

⁸⁰ See Bressman, *supra* note 70, at 603.

⁸¹ See *id.* at 616.

¹ See, e.g., *Harlow v. Fitzgerald*, 457 U.S. 800, 807–08 (1982); *Butz v. Economou*, 438 U.S. 478, 505–08 (1978); *Scheuer v. Rhodes*, 416 U.S. 232, 243–50 (1974); *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388, 407–11 (1971) (Harlan, J., concurring in the judgment); Louis L. Jaffe, *Suits Against Governments and Officers: Damage Actions*, 77 HARV. L. REV. 209, 216–17 (1963).

² 533 U.S. 194 (2001).