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CHRISTEN LINKE YOUNG

Agency Preemption Inputs in *Riegel v. Medtronic*

Federal administrative agencies have always had the authority to issue substantive regulations that conflict with, and therefore ultimately preempt, state law. In recent years, agencies have begun to assert a new and questionable kind of interpretative authority: taking a specific position on whether or not state law is preempted by an agency action. Later this year the Supreme Court will hear *Wyeth v. Levine*,[1] a Food and Drug Administration (FDA) case that is widely expected to tackle head-on the question of agency authority to determine when its regulations preempt state law. However, little-noticed language appearing in the Court's February 2008 decision in *Riegel v. Medronic*[2] may have significant implications for the upcoming *Wyeth* decision.

In 2007, the Court made its first foray into agency preemption authority in *Watters v. Wachovia Bank*.[3] Though the majority opinion failed to address the question, three dissenters considered and summarily rejected federal bank regulators' attempt to define the preemptive scope of the National Bank Act.[4] In *Wyeth*, the Court will revisit the question, determining what weight to give to an FDA regulation's preamble that purports to preempt all state tort suits alleging improper drug labeling. The recent decision in *Riegel* also involved preemption under an FDA-administered statute, the Medical Device Amendments of 1976 (MDA). *Riegel* technically turned on the scope of an express statutory preemption clause, but illuminating dicta in the majority opinion directly addressed the agency's role in defining preemption.

In these dicta, the Court considered a "savings" regulation promulgated by the FDA that *limited* the scope of the MDA's express preemption. Despite agreeing with the agency's conclusion, Justice Scalia questioned the FDA's

1. Levine v. Wyeth, 944 A.2d 179 (Vt. 2006), *cert. granted*, Wyeth v. Levine, 128 S. Ct. 1118 (2008).

2. 128 S. Ct. 999 (2008).

3. 127 S. Ct. 1559 (2007).

4. *Id.* at 1562-63; *id.* at 1573 (Stevens, J., dissenting).

authority to shape preemption. If the *Wyeth* Court reaches the opposite conclusion and allows the FDA's preamble to *expand* federal preemption, then the Court risks sending mixed messages to federal agencies—granting them authority to assert broad preemption, but skeptically reviewing any attempt to narrow preemptive scope. The discussion below illustrates the problematic implications of this outcome, first by describing *Riegel* and the "savings" regulation, and then by explaining how the *Wyeth* decision may be affected.

THE MDA, THE "SAVINGS" REGULATION, AND RIEGEL

The FDA gained regulatory authority over medical devices with the passage of the MDA in 1976. The MDA contains an express preemption clause that displaces any state law "requirement" that "relates to the safety or effectiveness" of a medical device and is "different from, or in addition to, any [federal] requirement."[5] The MDA also directs the agency to "save" certain state laws from preemption.[6]

Riegel v. Medtronic asked the Court to determine if common law tort liability constituted a "requirement" that was expressly preempted by the MDA's statutory language. Justice Scalia, joined by seven other Justices, concluded that it did, and the majority opinion largely coincided with the position advanced by the FDA in its amicus brief.[7]

Despite this general deference, however, the opinion was surprisingly hostile towards a 1978 FDA regulation—promulgated pursuant to express statutory authority—"saving" certain state law requirements from preemption. As codified, a portion of the regulation explains:

> [The MDA] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.[8]

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5. 21 U.S.C. § 360k(a) (2000).
6. Exemptions from Federal Preemption of State and Local Medical Device Requirements, 21 C.F.R. § 808.1 (2007).
7. Riegel, 128 S. Ct. at 1002.
8. 21 C.F.R. § 801.1(d)(1). This regulation is part of an unusual scheme that allows the FDA to grant state applications for "de-preemption" of particular laws and regulations. *See* 21 U.S.C. 360k(b); 21 C.F.R. §§ 808.53-808.101.

In *Riegel*, this rule was invoked by the petitioner, who claimed that common law tort liability was the kind of "general requirement," related to "products in addition to devices," that the FDA's regulation saved from preemption.[9] The FDA's brief rejected this assertion, and the Court agreed that the language did not extend to the petitioners' suit. Nevertheless, Justice Scalia was highly critical of the regulation. "Even assuming," he wrote, "that this regulation could play a role in defining the MDA's preemptive scope, it does not provide unambiguous support for the [plaintiff-petitioners'] position."[10] Justice Scalia was highly skeptical of both the agency's ability to limit the extent of federal preemption and the reasoning behind its interpretation. The FDA insisted that, while electrical codes and the U.C.C. do not act directly on the device, tort duties "directly regulate the device itself."[11] Scalia dismissed this logic, "since the same could be said" of the requirements that the regulation explicitly saves.[12]

In these passages, Scalia does three things. First, he carefully refuses to recognize any FDA authority in defining preemption. Second, he rejects the agency's attempt to codify a sensible division between "direct" and "indirect" regulation. Finally, he arguably goes beyond the *Watters* dissent, which he joined, to circumscribe the FDA's power to determine preemption. The *Watters* dissent also rejected an agency's assertion of preemption authority. However, in that case and unlike in *Riegel*, Congress had not authorized the agency to define preemption, and the agency had not specifically declared whether its rule would have preemptive effect. Perhaps most importantly, while the *Watters* regulation ran afoul of the Court's long-standing presumption against preemption, the savings regulation was the very embodiment of this presumption and should have been entitled to greater respect.

IMPLICATIONS FOR WYETH

Wyeth v. Levine considers the scope of *implied* preemption under the federal scheme regulating drugs, which lacks express statutory preemption language.[13]

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9. *See* Riegel, 128 S. Ct. at 1010.

10. *Id.*

11. *Id.* (quoting Brief for United States as Amicus Curiae Supporting Respondent at 28, Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008) (No. 06-179), 2007 WL 3231418, at *28) (internal quotation marks omitted).

12. *Id.*

13. Levine v. Wyeth, 944 A.2d 179 (Vt. 2006), *cert. granted*, Wyeth v. Levine, 128 S. Ct. 1118 (2008).

Although injured plaintiffs have successfully sued pharmaceutical manufacturers for decades, in 2006 the FDA promulgated new labeling rules, which included a preamble insisting that the regulation preempted state tort law claims.[14] Thus, the *Wyeth* Court must consider what weight to give to the agency's novel judgment regarding preemption.

Indeed, *Wyeth* presents the Court with facts somewhat analogous to *Watters*, and the preemptive preamble is less defensible than the *Riegel* saving regulation for three important reasons. First, the savings regulation in *Riegel* is a legislative rule,[15] while the *Wyeth* language appears in a preamble and has no formal legislative effect.[16] Second, the 1978 savings regulation was preceded by a proposed rulemaking that explained the agency's choice and was accompanied by an analysis of several comments addressing the issue. In the 2006 preamble, however, the agency went out of its way to avoid any public consideration of preemption. The proposed rule contained no hint of preemption language, and the federalism impact statement accompanying the proposal stated that it had no effect on state law.[17] Finally, the MDA savings regulation has the general effect of limiting preemption, while the 2006 language carves out the widest possible preemptive space.

In light of the *Riegel* Court's treatment of the 1978 savings regulation, what can we expect from *Wyeth* and the preemptive preamble? In the last two years, the Justices have twice addressed agencies' preemptive authority—once in dissent and once in dicta—and on both occasions rejected the legitimacy of the agency's action. Indeed, in *Riegel*, Scalia dismissed a formal and thoroughly explained interpretation even though he ultimately agreed with the agency's straightforward conclusion. *Wyeth* presents a much more implausible agency assertion of authority than that found in *Riegel*. An entirely novel assertion of preemption is presented in a preamble; surely it is reasonable to infer that the Court would also reject agency authority in this context. This inference almost certainly holds for the three Justices—Roberts, Scalia, and Stevens—who joined the *Watters* dissent along with the *Riegel* majority.

But for the other Justices, *Riegel* may highlight a disturbing possibility. If the Court relies on the agency's preamble in *Wyeth* and holds the state law

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14. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

15. *See* Exemptions from Federal Preemption of State and Local Medical Device Requirements, 21 C.F.R. § 808.1 (2007).

16. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.

17. *See* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 254 (2007).

preempted, then successive majorities will have frowned upon the FDA's attempts to *limit* preemption in *Riegel*, while welcoming its attempts to *expand* it in *Wyeth*. In the hands of the Court, agency action defining preemptory authority risks becoming a one-way ratchet–fully applicable in the service of strong federal preemption, but unable to narrow the preemptive scope when it seeks to create a safe harbor for state law. In the face of the Court's oft-repeated commitment to a "presumption against preemption,"[18] and its recent adherence to the principles of federalism more generally, this outcome seems both backwards and inappropriate.

There is, of course, another option, which may reflect the intent behind Justice Scalia's dismissive language in *Riegel*. Scalia's assessment of the 1978 regulation may suggest to the *Wyeth* Court that ill-considered preambles asserting astonishingly broad preemption are not the primary way agencies should help shape the contours of state law preemption. In heeding this message, the Justices could use *Wyeth* as an opportunity to craft a principled test for agency preemption inputs, faithfully adhering to precedent on preemption and sending a clear signal to federal agencies.

Christen Linke Young is a second-year student at Yale Law School. *Special thanks to Professors William Eskridge, Thomas Merrill, and Ted Ruger, and to Jon Donenberg.*

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18. *Cf.* Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. (forthcoming 2008).