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REPORT FROM WASHINGTON

Supreme Court Hears Its Second Significant Preemption Case This Term

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The United States Supreme Court heard oral argument yesterday in *Wyeth v. Levine*, No. 06-1249 – its second significant preemption case this term – in which the Court will address the preemptive reach of the Federal Food, Drug, and Cosmetic Act (the "FDCA"). Specifically at issue is whether the Food and Drug Administration's (the "FDA") drug approval process impliedly preempts state tort laws that would impose duties on drug manufacturers exceeding those set forth by the FDA pursuant to the FDCA. Although the Court previously examined the preemptive reach of the Medical Device Amendments to the FDCA in *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996), and *Riegel v. Medtronic Inc.*, 128 S. Ct. 999 (2008), the Court has yet to determine whether the FDCA's drug approval process creates a "floor" onto which states can place additional duties on pharmaceutical companies, or both a "floor" and a "ceiling" between which no additional state tort duties may exist. The Court's decision in *Levine* has been much anticipated because of its potential to resolve the important issue of whether pharmaceutical companies may be liable for negligence and failure-to-warn claims under state law where the drugs and warnings at issue satisfied the FDA's approval process.

BACKGROUND

Plaintiff Diana Levine sued Wyeth for failure-to-warn product liability and negligence, alleging that Wyeth failed to provide adequate warnings relating to the intravenous use of its anti-nausea drug Phenergan. Plaintiff claimed that the drug caused devastating necrosis, resulting in gangrene, after a medical professional attempted to inject the drug into a vein using the intravenous-push method rather than using alternative methods like intravenous-drip or injecting the drug directly into muscle tissue.[1] The injection inadvertently exposed an artery to the drug and ultimately required the amputation of Plaintiff's arm below the

[1] Intravenous push is where a medical professional "pushes" the drug into a vein directly from a syringe, as opposed to placing the drug in a "drip" bag that uses gravity to introduce the drug into a patient's vein.

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JUSTICE SOUTER

elbow. Although the FDA explicitly approved the precise content of the Phenergan label warning against, but not contraindicating, intravenous administration of the drug, the Vermont jury ruled in favor of Plaintiff on both claims.

After the verdict, Wyeth renewed its motion for judgment as a matter of law on the basis of preemption, arguing that unilaterally changing Phenergan's warning label to conform with state law would have subjected Wyeth to liability under the FDCA for misbranding and would have created a conflict between complying with state law and federal law. Furthermore, allowing juries in state courts to second-guess the FDA-approved warning labels would pose an obstacle to the federal drug safety regime. Rejecting Wyeth's preemption arguments, the trial court held that tort liability creates "tension [but] does not amount to a direct conflict with the FDA labeling requirements."

On appeal to the Vermont Supreme Court, Wyeth again argued that Vermont tort law as applied in this case would require Wyeth unilaterally to change the language of Phenergan's warning label, creating a direct conflict with federal law and obstructing the FDA's purpose of simultaneously evaluating a drug's safety while preserving a physician's freedom to administer a drug as he or she sees fit. Because Wyeth conceded that the FDCA does not expressly preempt state tort actions, and that Congress did not intend the FDCA to occupy the entire field of prescription drug regulation, Wyeth argued that Plaintiff's claims were impliedly preempted due to their conflict with the FDA's drug and label approval. The Vermont Supreme Court disagreed, affirming the trial court's ruling that additional state law tort duties do not create an actual conflict with the FDA's drug labeling regulations. According to the Vermont Court, Wyeth "was free... to strengthen the warning without prior FDA approval" because "[t]here was no evidence that the FDA intended to prohibit defendant from strengthening the Phenergan label" pursuant to an FDA regulation, 21 C.F.R. § 314.70, which the Vermont Court interpreted as allowing drug companies to change drug labels without prior FDA approval to add to or strengthen its warning. Further, the Vermont Supreme Court endorsed the reasoning of some recent U.S. district courts that Congress intended the FDCA to create a "floor, not a ceiling, for state regulation."

Significantly, the Vermont Supreme Court declined to give any weight to the FDA's 2006 "Preemption Preamble" contained in an FDA release on *Requirements on Content and Format of Labeling Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006), in which the FDA changed its prior position that state law failure-to-warn claims were not preempted. The Preamble announced the agency's position that state law tort claims for failure to include warnings on labels that had received full FDA approval were preempted, stating that the FDA's approval constituted both the "floor" and "ceiling" for further state requirements on labeling.[2] The Court refused to provide the FDA's 2006 interpretation with full administrative agency deference under *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984), finding that (1) the 1962 amendment

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JUSTICE KENNEDY

[2] The FDA's 2006 statement was a departure from its prior support for the existence of complementary state tort law obligations. See 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998) ("[the] FDA's regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements.").

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CHIEF JUSTICE ROBERTS

"[The jury's verdict has] the effect... [of] imposing a limitation on the label."

CHIEF JUSTICE ROBERTS

to the FDCA clearly and unambiguously expressed Congress's intent to preempt only state laws in "direct and positive" conflict with the FDCA, and the state tort duties imposed here created no such conflict because they merely imposed additional complementary requirements, and (2) Ms. Levine's injury occurred before the date of the FDA's Preemption Preamble. While the Vermont Supreme Court held that the FDA's interpretation was entitled to "some respect" under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), it also held that the agency's position was unpersuasive.

SUMMARY OF THE ARGUMENT

Before the Supreme Court yesterday, Petitioner Wyeth argued that Respondent Levine's claims are preempted because the FDA repeatedly concluded that Phenergan as marketed was "safe and effective." Petitioner further argued that state juries may not overturn the carefully considered position of the FDA, the agency charged with determining the appropriate balance of risk and benefits associated with pharmaceuticals.

Several Justices questioned why Petitioner did not alter its labeling of Phenergan to conform to both its federal regulatory and state tort law obligations. Specifically, Justice Kennedy noted, "I could design a label that's completely consistent [with both federal and state law obligations]." Petitioner responded that the Vermont trial court's ruling requires Wyeth to include a contraindication to administering the drug via intravenous-push, whereas the FDA has explicitly approved of that method of administration. Because "[Wyeth] could have gone back to the FDA at any time... and it simply didn't do it," Justice Souter asked, "where is the conflict?" Petitioner responded that the FDA previously had rejected a stronger warning concerning the intravenous administration of the drug.

The Justices also questioned Petitioner concerning whether the FDA had considered the discrete question of whether intravenous-push administration of Phenergan – as opposed to intravenous administration in general – was particularly dangerous. When Petitioner answered that it had, Justice Ginsburg asked: "how could the benefit [of intravenous-push administration] outweigh that substantial risk?" Justice Alito similarly questioned: "[h]ow could the FDA [have] concluded that IV push was safe and effective" when Phenergan was not a life-saving drug?

The United States appeared as an *amicus* in support of Petitioner, arguing for preemption. When Justice Ginsburg asked whether the FDA's position had changed, the Government replied that FDA has never allowed pharmaceutical companies to alter its drug labels without new information. In response to Justice Scalia's questioning, the Government noted that state tort remedies are appropriate where there is no conflict between federal and state requirements, and where liability is based on new information that had never been provided to the FDA.

Respondent Levine argued that Wyeth knew or should have known of the risks posed by intravenous-push administration of the drug, yet failed to prevent any resulting harm. Respondent also claimed that the FDA had not considered the discrete risk associated with intravenous-push administration, and that 21 C.F.R. § 201.80 requires drug manufacturers to discover and respond to new problems that had not been considered by the FDA.

Justice Scalia interjected that the regulation references only risks "that the FDA has not considered." Respondent argued that, while the FDA was aware of

different methods of administration, including intravenous-push, it did not separately analyze the risks associated with each method. Chief Justice Roberts noted that: "When [the FDA] determine[s] that it's safe to use under those circumstances that necessarily includes a consideration of the risk. People can say it's safe for you to walk down the sidewalk. That doesn't mean there is no risk that you get hit by lightening or something else." The Chief Justice also observed that the jury had concluded that the intravenous-push administration was improper, which has "the effect... [of] imposing a limitation on the label."

Chief Justice Roberts then questioned whether there must be new information present for Respondent to avoid preemption. Although Respondent maintained additional information was not necessary, counsel conceded that there would be preemption had the FDA considered the risks versus benefits of the intravenous-push administration in approving Phenergan's labeling. While acknowledging that the FDA had mentioned intravenous-push in communications with Petitioner, Respondent claimed that the FDA had not weighed the comparative risks and benefits of intravenous-push versus intravenous-drip administration in its approval of Phenergan's label.

IMPLICATIONS

In *Levine*, the United States Supreme Court is set to determine whether the FDA's drug approval process impliedly preempts state law tort claims and, if so, to what extent. In the event the Court agrees with Wyeth that FDA regulation serves as both a floor and a ceiling – and thus finds conflicting state law claims preempted unless pharmaceutical companies fail to pass on to the FDA information about new risks on the severity or frequency of side-effects – pharmaceutical companies need only comply with the FDA's drug approval regulations. If, on the other hand, the Court determines that the FDA regulations merely serve as a floor, those companies may still be liable for common law torts, such as products liability and negligence in the labeling of their drugs, for failure to provide warnings over and above those mandated by the FDA. The questions at oral argument revealed that the Court will be divided when it hands down its opinion, creating the possibility of a less sweeping decision than may have been anticipated. As in a number of prior Supreme Court cases involving important issues of social policy, this one may well be shaped by the Justices in the center.

Of note, this is the fourth significant products liability related preemption case the United States Supreme Court has heard over the last two years. Most recently, the Court on October 6, 2008 heard arguments in *Altria Group, Inc. v. Good*, No. 07-562, a case likely to clarify the extent to which the Federal Cigarette Labeling and Advertising Act and Federal Trade Commission's regulations preempt state law claims. Last term, the Court's decision in *Riegel v. Medtronic Inc.*, No. 06-179, found that state law tort duties are "requirements" under an express preemption provision in the Medical Device Amendments to the FDCA, and thus are preempted when they differ from, or are in addition to, the duties imposed by the FDA after a Class III medical device undergoes the "rigorous" full pre-market approval process. Although the Supreme Court also heard arguments in *Warner-Lambert v. Kent,* No. 06-1498, which similarly involved the FDCA, it issued a summary affirmance due to a 4-4 split (Chief Justice Roberts had recused himself).

For further information about this case and oral argument, please feel free to contact members of the Firm's Litigation Department, including:

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