FEDERAL PRE-EMPTION'S IMPACT ON PRODUCT LIABILITY

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Medical Devices, Pharmaceuticals, and Federal Preemption: A Look at the Legal Landscape in Light of Riegel and Levine

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I. Federal Preemption of State Law Claims for Medical Devices: the Supreme Court's Decision in Riegel v. Medtronic

In the recent case of Riegel v. Medtronic, Inc.,[1] the Supreme Court held 8-1 that state common law tort claims challenging the "safety or effectiveness" of certain medical devices are preempted by the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA). 21 U.S.C. 360c *et seq.* More specifically, the Court held that common law claims of strict liability, breach of implied warranty, and negligence as to medical devices entering the market via the premarket approval (PMA) process fall within the ambit of the MDA's express preemption provision, which prohibits states from establishing or maintaining any requirement relating to the safety or effectiveness of medical devices that is "different from or in addition to" those requirements created pursuant to the FDCA.[2] In reaching its decision, the Court analyzed the nature of these state law claims in light of the language of the statute's preemption provision, ultimately concluding: (1) that the Food and Drug Administration's (FDA) premarket approval process for medical devices constitutes an FDCA "requirement" within the meaning of the provision; (2) that the common law duties created by state tort law constitute state "requirements" within the meaning of the provision; and (3) that these state requirements are "different from or in addition to" the FDCA requirement of premarket approval.

While the Court in Riegel definitively established that the three common law claims at issue in that case—strict liability, breach of implied warranty, negligence—are no longer viable as to medical devices which entered the market through the FDA's premarket approval process, the decision leaves several issues in this area of the law unresolved. Among those questions remaining in the wake of Riegel, three are particularly noteworthy. First, are the common law claims involved in Riegel also preempted where the medical device at issue entered the market through substantial equivalence review (as opposed to premarket approval)? Second, even where the device at issue underwent the premarket approval process, are there any state law claims that remain viable or are all such claims preempted by the MDA? Finally, what impact if any will the Court's decision have on state law claims as to pharmaceuticals?

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[1] 128 S.Ct. 999 (2008)

[2] 21 U.S.C. §360k(a)

II. Common Law Claims as to Medical Devices Entering the Market Through Substantial Equivalence Review

There are two standard ways by which a proposed medical device may be cleared by the FDA and enter the market: premarket approval and substantial equivalence review.[3] While the MDA generally requires that all new medical devices undergo the rigorous premarket approval process, Congress carved out an important exception: in order to prevent those devices already on the market at the time of the statute's enactment from having an unfair advantage over newly emerging competitors, new devices determined to be "substantially equivalent" to those already on the market were exempt from the premarket approval process.[4] Given that the vast majority of new devices currently enter the market via this alternative route, the determination of whether the MDA's preemption provision extends to common law claims as to "substantially equivalent" medical devices is of considerable consequence.

While the Court's explicit holding in Riegel was limited to cases in which the medical device at issue underwent premarket approval, a basic analysis of the opinion's reasoning in light of recent precedent suggests that the Court would find that the MDA preemption provision does not apply to state common law claims as to those devices that entered the market via substantial equivalence review. As explained above, in reaching its ultimate conclusion in Riegel that the plaintiff's common law claims were preempted by the MDA, the Court first took up the question of whether the FDA's premarket approval process constituted a "requirement" within the meaning of the MDA's preemption provision, explaining that such was a necessary but not sufficient condition for finding the claims preempted.

The Court addressed this same question as to substantial equivalence review in Medtronic, Inc. v. Lohr,[5] concluding that substantial equivalence was a "qualification" for exemption as opposed to a requirement.[6] Given that the Court dutifully applied the Lohr opinion's rationale in its treatment of premarket approval in Riegel earlier this year, it seems clear that the Court has no intentions of abandoning its previous holding that substantial equivalence review does not constitute a "requirement" within the meaning of the MDA's preemption provision. Since the MDA's preemption provision applies only where there is an FDA requirement at stake, it appears likely that the Court would find that where the medical device at issue entered the market via substantial equivalence review, a plaintiff's state common law claims are not preempted.

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[3] Stern, Robert L., *Supreme Court Practice: For Practice in the Supreme Court of the United States*, p. 1079 (2002)

[4] 21 U.S.C. §360c(f)(1)(A)

[5] 518 U.S. 470 (1996)

[6] Id. at 493-494.

III. Viability of Other State Law Claims as to PMA Medical Devices

Since the Riegel Court declined to analyze the dicta of the lower court which stated that "parallel" state law claims are not preempted under the MDA[7], plaintiffs seeking to circumvent Riegel preemption and maintain state law claims against manufacturers of PMA medical devices immediately began incorporating such parallel claims into their complaints. Perhaps the claim most frequently advanced by such plaintiffs is that the device manufacturer committed fraud. However, because plaintiffs can almost never show that the manufacturer made representations directly to the injured party, they are left to plead facts alleging that the manufacturer withheld or misrepresented information in dealing with the FDA. As a result, courts routinely construe these claims as amounting to fraud-on-the-FDA and, in turn, hold that the claims are preempted[8] under Buckman Co. v. Plaintiffs' Legal Comm..[9]

Some plaintiffs have also brought state law claims of negligence per se contending that such claims are parallel in nature and thus not preempted under Riegel. While plaintiffs face a number of potential problems in attempting to maintain a claim of negligence per se in the context of PMA medical devices, two in particular are worth highlighting. First, the requirement that a plaintiff must show a causal link between the alleged violation of FDA regulations and the injury suffered can be difficult to satisfy in medical device liability cases.[10] Second, many states do not recognize negligence per se as an independent cause of action, instead allowing it only when there is a pre-existing common law duty underlying the claim.[11] Ultimately, it appears that these two obstacles will make it considerably difficult for plaintiffs to successfully sustain state law claims of negligence per se as a means of avoiding preemption under Riegel.

Even if a plaintiff can make the showings required to sustain state law claims rightly construed as parallel, there is a reasonable argument to be made that these claims remain not viable as also preempted by the FDCA. Section 337(a) of the Act states that "all such proceedings for the enforcement, or to restrain violations of this chapter shall be by and in the name of the United States."[12] Because this provision implicitly prohibits private enforcement of

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[7] 128 S. Ct. at 1011.

[8] *See, e.g.*, McCutcheon v. Zimmer Holdings, Inc., 2008 WL 3153442 (N.D. Ill. 2008); McGuan v. Endovascular Technologies, Inc., 2008 WL 3139418 (Cal. Super. 2008); O'Shea v. Cordis Corp., 2008 WL 3139428 (Fla. Cir. 2008).

[9] 531 U.S. 341 (2001).

[10] Jim Beck and Mark Hermann, *Drug and Device Law: Riegel at (Almost) Six Months* (*available at* http://druganddevicelaw.blogspot.com/2008/08/riegel-at-almost-six-months.html) (accessed Oct. 14, 2008).

[11] *See, e.g.*, Talley v. Danek Medical, Inc., 179 F.3d 154, 158 (4th Cir. 1999). Accord Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1017 (8th Cir. 2004); King v. Danek Medical, Inc., 37 S.W.3d 429, 460 (Tenn. App. 2000).

[12] 21 U.S.C. §337(a)

the statute's requirements and any state law claim (parallel or otherwise) could be understood as an attempt to engage in such private enforcement, it is conceivable that a court could conclude that even parallel state law claims are preempted under the statute.[13]

IV. Levine and the Fate of State Law Claims for Pharmaceuticals

While the Court's decision in Riegel both answered and engendered important questions regarding preemption of state law claims for medical devices, it did little to clear up the legal landscape as to such claims where pharmaceuticals are concerned. Unlike the MDA, the FDCA sections concerning regulation of pharmaceuticals include no express preemption provision. As a result, to the extent there is an argument in favor of federal preemption of state law pharmaceutical claims, it must rely on traditional formulations of implied preemption. Put in more simple terms, for a state law pharmaceutical claim to be preempted, it must be shown to conflict with federal law.

On Monday, November 3, 2008 the United States Supreme Court will hear oral arguments in Wyeth v. Levine,[14] and the Court's decision in the case should go a long way towards defining the extent to which state law claims for pharmaceuticals are preempted under the FDCA. At issue in the case specifically is whether a plaintiff who alleges to have been injured by a pharmaceutical may maintain a claim against the drug manufacturer for failure to warn or whether such a claim is preempted in light of the FDA's regulations regarding drug labeling.

The failure to warn claim at issue in Levine alleges that the label used by Wyeth, the manufacturer of the drug Phenergan, insufficiently communicated the risks of administering the drug via the "IV push" method, and the label's insufficient warning resulted in plaintiff's being injured. Defendant Wyeth takes the position that, irrespective of whether the label's warning was sufficient, plaintiff's failure to warn claim is preempted under the FDCA in two ways.[15] First, Wyeth argues, it would have been impossible for the company to have complied with both its alleged state law duty to strengthen the label's warning as to the IV push method without violating the FDCA. As the Court held in Fidelity Fed. Sav. & Loan v. de la Cuesta,[16] state law is preempted when "compliance with both federal and state regulations is a physical impossibility."[17] Strengthening the label's warning while complying with federal law is just such a physical impossibility, Wyeth contends, as the FDCA generally prohibits a manufacturer

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[13] Jim Beck and Mark Hermann, *Drug and Device Law: More Thoughts About "Parallel" Requirements Claims and Preemption* (*available at* http://druganddevicelaw.blogspot.com/2008/06/more-thoughts-about-parallel.html) (accessed Oct. 14, 2008).

[14] 944 A.2d 179 (Vt. 2006).

[15] Brief for Petitioner, 2008 WL 2273067 at 26 (U.S. 2008).

[16] 458 U.S. 141 (1982).

[17] Id. at 153.

from unilaterally changing a drug label after its approval by the FDA. As a result, the state law duty advanced by the plaintiff conflicts with federal law, and plaintiff's state law claim is preempted.

The other way in which Wyeth argues that plaintiff's state law claim is preempted by federal law is on the basis that it undermines the purpose of FDCA[18] and, as the Court held in Hines v. Davidowitz,[19] claims that "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" are preempted. According to Wyeth, the regulatory regime established by Congress in the FDCA charges the FDA, in the drug labeling approval process, with making judgments intended to balance the relative risks and benefits of a drug and its uses. Allowing state failure to warn claims such as the one at issue in Levine, Wyeth argues, would "displace the FDA's expert judgment and substitute the verdicts of lay jurors in fifty States who consider drug safety after the fact…focusing on a single patient's catastrophic injury, rather than on the potential benefits…to the public as a whole" and this, in turn, "will produce more risk-averse determinations" by the FDA.[20]

Meanwhile, Plaintiff Levine contends, as the Vermont Supreme Court held, that her state law failure to warn claim is not preempted by the FDCA. In support of her position, Levine points out that courts have been entertaining state law failure to warn claims in the 70 years since the passage of the FDCA and, while Congress took pains to include an express preemption provision for medical devices when it amended the FDCA in 1976, it included no such provision for pharmaceuticals either then or in the numerous other times it has amended the statute.[21] Levine also argues that there is no basis for finding implied conflict preemption in this case, as neither is compliance with both state and federal law impossible nor does the state law duty pose an obstacle to Congress's purposes in enacting the FDCA. According to Levine, federal law did not prohibit Wyeth from including a stronger warning against IV push administration on its label, alleging that the FDA's Changes Being Effected ("CBE") regulation[22] explicitly authorizes manufacturers to change labeling post-approval.[23] Additionally, Levine contends, the state law duty underlying her failure to warn claim complements federal labeling requirements by "encouraging manufacturers to discover and to disseminate the most current information about the risks of their products."[24]

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[18] Brief for Petitioner, *supra*.

[19] 312 U.S. 52, 67 (1941).

[20] Brief for Petitioner, *supra.*

[21] Brief for Respondent, 2008 WL 3285388 at 20 (2008).

[22] 21 C.F.R. §314.70(c)(6).

[23] Id.

[24] Id.

Ultimately, the Court's disposition of this case will likely turn on its interpretation the FDA's CBE regulation. Should the Court agree with Levine and the Vermont Supreme Court that the regulation provided Wyeth the opportunity to strengthen the warning on Phenergan's label, it seems unlikely that the Court will conclude that there is implied conflict preemption with respect to Levine's state law claim. However, should the Court adopt the interpretation advanced by Wyeth—that the regulation provides for a temporary change only when new risk information about a drug becomes available—there appears to be a good chance the Court would find Levine's failure to warn claim preempted under the FDCA.

In either case, it is not yet clear how far reaching the Court's decision will be. Even if the Court finds Levine's claim to be preempted, to the extent it confines its holding to the facts of the case, future plaintiffs could still bring and have adjudicated other state law claims such as for manufacturing defects. If, however, the Court takes a longer view of federal preemption in the context of pharmaceuticals, its decision in Levine could prove monumental in determining the scope of liability to which drug manufacturers will be exposed in the future.

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Lee was the first law student recruited by the firm in 1992 and has been a partner since 1999.

Lee has tried serious wrongful death and personal injury cases to defense verdicts. Currently, Lee spends most of his time defending high exposure personal injury litigation, especially products liability, pharmaceutical and medical device cases. He also, spends a significant amount of time handling commercial cases on both the plaintiff and defense side. Lee is currently serving as national coordinating counsel for a national biomedical service company. He is frequently called on by major excess insurance carriers as cases approach trial to assist in the settlement and/or trial of high exposure cases. In that role, Lee often serves as appellate counsel at trial to handle legal issues and preserve the record, in the event of an appeal. He is admitted to practice in all State and Federal courts in Alabama, as well as the Eleventh Circuit Court of Appeals and the United States Supreme Court.

Lee served as Co-Chair of the Alabama Defense Lawyers Association's Trial Academy from 1995 to 1998. He is a member of the American and Birmingham Bar Associations, the Defense Research Institute and the Alabama Defense Lawyers Association. Lee is a devoted alumnus of Washington & Lee University. After serving as president of the Nashville and Birmingham alumni chapters, Lee served on the Board of Directors of the Washington & Lee Alumni Association from 2002-06 and served as its president in 2005-2006.

Lee is a member of Saint Stephen's Episcopal Church and is the proud father of three children who have unfortunately inherited their father's lawyering skills at a very young age.

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