Article originally published in 17 THE DEFENDER, Fall 2009, at 22 (publication of the North Carolina Association of Defense Attorneys).

Recent Developments in Federal Preemption of Pharmaceutical Drug and Medical Device Product Liability Claims

Bryan G. Scott
Elizabeth K. Strickland

Few areas of law have proven more dynamic over the last few years than the interplay between state tort laws and the federal regulation of pharmaceutical drugs and medical devices. During its last two terms, the United States Supreme Court has issued three separate opinions addressing federal preemption of state law claims under the Federal Food, Drug, and Cosmetic Act. The results in these cases and other recent developments in the drug and device field have widespread implications for product liability practitioners in North Carolina and beyond. This article provides a brief survey of the caselaw impacting common law claims against drug and device manufacturers, as well as federal legislative and executive actions that may continue to transform this increasingly important and complex area of the law.

I. Regulation of Drugs and Medical Devices under the Federal Food, Drug, and Cosmetic Act

A. Federal Food, Drug, and Cosmetic Act

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., in response to concerns about unsafe drugs and fraudulent marketing. The FDCA's key innovation over previous product regulation laws was a provision for the premarket approval of new drugs. Wyeth v. Levine, 555 U.S. ___, 129 S. Ct. 1187, 1195 (2009). The FDCA requires every drug manufacturer to submit a new drug application to the Food and Drug Administration (FDA) for review, and prohibits the manufacturer from distributing the drug until that application is approved. Id. The Act was later amended in 1962 to also require the manufacturer to prove that the drug is safe for use before it enters the market. Although this amendment gave the FDA great power, Congress took strides to preserve state law, providing that no "provision of State law" would be invalidated by the amendments except upon a "direct and positive conflict" with the FDCA. Id. at 1195-96. In 2007, Congress again amended the FDCA to make it clear that manufacturers remain responsible for updating their labels and to grant the FDA authority to require manufacturers to change drug labels based on safety information obtained after a drug's initial approval. Id. at 1196.

In most situations, the manufacturer can make substantive changes to a previously-approved drug label only after submitting a supplemental application explaining the basis for the change and obtaining FDA approval. 21 C.F.R. § 314.70. However, where the purpose of the change is to add or strengthen certain warnings or information intended to increase the safe use of the product, or to omit misleading information, the "Changes Being Effected" process (CBE) allows certain changes to be made upon submission of a supplemental application, but before FDA approval. 21 C.F.R. § 314.70(c)(6)(iii). If the manufacturer adds risk information without prior FDA approval, it runs the risk that the FDA may later deny approval for the supplement,

opening the door for an enforcement action for misbranding if the new information makes the labeling false or misleading under the Act. 21 U.S.C. § 352. In practice, therefore, manufacturers typically consult with the FDA before adding risk information to drug labeling. See 71 Fed. Reg. at 3934.

B. The Medical Device Amendments of 1976

Although the FDCA has always imposed premarket controls requiring FDA review of new drugs before their entry on the market, it did not similarly regulate the introduction of new medical devices. Following a series of high-profile medical device failures in the 1960s and 1970s, including, notably, the Dalkon Shield intrauterine device, Congress amended the FDCA through the Medical Device Amendments of 1976 (MDA) to impose a detailed federal regulatory scheme for medical devices. Riegel v. Medtronic, Inc., 552 U.S. __, 128 S. Ct. 999, 1003 (2008). The MDA established three classes of medical devices, each with its own level of required oversight depending on the risks presented to the public. Of these, Class III includes those devices presenting the greatest risk of harm and, therefore, receives the most stringent treatment. 21 U.S.C. § 360c(a)(I)(C). Class III is the only category of medical devices for which the MDA requires premarket approval. Id.

The premarket approval process under the MDA is extremely thorough and requires manufacturers to submit detailed information about the safety and effectiveness of their devices, which is then subject to a rigorous review by the FDA that takes, on average, 1200 hours per submission. Medtronic v. Lohr, 518 U.S. 470, 477 (1996) (citing Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100-34), p. 384 (1987)). The MDA requires FDA approval before a manufacturer can alter a previously approved device's design specifications, manufacturing processes, labeling, or any other attribute that would affect the device's safety or effectiveness. Riegel, 128 S. Ct. at 1005 (citing 21 U.S.C. 360e(d)(6)(A)(i)). If a manufacturer wants to make such a change, it must submit an application for supplemental premarket approval, which the FDA evaluates under largely the same criteria as the initial application. Id. (citing 21 U.S.C. 360e(d)(6); 21 CFR § 814.39(c)).

When Congress enacted the MDA, it essentially grandfathered many pre-existing device types already on the market from having to undergo the premarket approval process. Lohr, 518 U.S. at 477-78; 21 U.S.C. § 360e(b)(1)(A). To prevent the manufacturers of these devices from enjoying an unfair competitive advantage, Congress also relieved similar new products from premarket approval requirements if the FDA has found that they are "substantially equivalent" to a grandfathered device. Id.; 21 U.S.C. § 360e(b)(1)(B). The new devices meeting this test are instead subject to a limited form of review called the "premarket notification" process, also known as the "§ 510(k) process" after the number of the section in the original act. Id.; 21 U.S.C. § 360(k). The FDA's review of new devices under the premarket notification process is far less stringent, requiring on average only 20 hours. Id. (citing Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100-34), p. 384 (1987)).

Unlike the rest of the FDCA, which does not speak directly to federal preemption of state law, Congress included in the MDA an express preemption clause stating that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

II. Recent Supreme Court Decisions of Relevance

Against this regulatory landscape, the United States Supreme Court considered three appeals over its last two terms directly impacting federal preemption doctrine in the context of drug and medical device product liability claims: Riegel v. Medtronic, Inc., Warner-Lambert Co. v. Kent, and Wyeth v. Levine.

Important to each of these opinions are two fundamental principles that guide preemption law. First, "the purpose of Congress is the ultimate touchstone in every preemption case." Wyeth, 129 S. Ct. at 1194 (quoting Lohr, 518 U.S. at 485). Second, in all preemption cases, the Court begins with the assumption that the police powers of the states are not to be superseded by federal statute "unless that was the clear and manifest purpose of Congress." Id. (quoting Lohr, 518 U.S. at 485) (citation omitted).

A. Riegel v. Medtronic, Inc.: Preemption of Claims Involving Class III Medical Devices Receiving FDA Premarket Approval

At issue in Riegel v. Medtronic, Inc. was whether the MDA's express preemption clause, 21 U.S.C. § 360k(a), bars common law claims challenging the safety or effectiveness of medical devices given premarket approval by the FDA. Riegel v. Medtronic, Inc., 552 U.S. ___, 128 S. Ct. 999, 1011 (2008). The Supreme Court held that it does, echoing the conclusion of the majority of the circuit courts to consider the issue. See Rattay v. Medtronic, Inc., 482 F. Supp. 2d 746, 757-58 (N.D. W. Va. 2007) (collecting cases).

The plaintiff in Riegel was seriously injured when an Evergreen Balloon Catheter, a Class III device, ruptured while inserted in his coronary artery. Riegel sued Medtronic, the manufacturer of the balloon catheter, in federal district court. The district court held that the MDA preempted his state common law claims brought under strict liability, implied warranty, and negligence theories. The United States Court of Appeals for the Second Circuit affirmed the dismissal, concluding that "Medtronic was 'clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individually, federally approved' premarket approval application," and Riegel's claims "were pre-empted because they 'would, if successful, impose state requirements that differed from, or added to' the device-specific federal requirements." Riegel, 128 S. Ct. at 1005.

The Supreme Court agreed. Due largely to the rigorous safety review required, the Court held that the premarket approval process imposes the type of "specific requirements applicable to a particular device" triggering the MDA preemption clause in Section 360k(a). The majority in

Riegel refused to speculate as to congressional motives behind § 360k(a) or to consider the FDA's amicus position supporting preemption, instead basing its decision on what it considered the plain language of the provision. It also readily dispatched the plaintiffs' argument that common law duties were not "requirements" maintained "with respect to devices," noting that nothing in § 360k(a) suggests that the state requirement "must apply *only* to the relevant device, or only to medical devices and not all products and all actions in general."

At least for now, the Court's opinion in Riegel makes clear that MDA preemption is a viable defense to most common law claims involving Class III medical devices that have received FDA premarket approval (although, as described in Section III.A. below, pending legislation may change that result). Notably, the decision does not affect state law claims against Class I and II medical devices, which are not subject to premarket approval and not included within the scope of § 360k(a). It also bears noting that the Supreme Court in Medtronic v. Lohr had already held that the MDA does not preempt common law design defect claims against even Class III medical devices that enter the market following the less stringent §510(k) premarket notification process, nor claims alleging violations of generally applicable manufacturing and labeling duties not directed specifically to any particular medical device. The Court also confirmed in Riegel that the MDA does not preempt parallel state law claims—damages claims authorized by state law for violations of the federal regulations themselves—that do not impose on device manufacturers requirements that differ from or add to the federal scheme.

The Supreme Court's decision in Riegel did little to change existing law here in the Fourth Circuit or North Carolina. The Fourth Circuit had not previously addressed whether the premarket approval process triggered preemption under § 360k(a), although it had forecasted that the provision would bar state law claims imposing any "differing or additional state-law requirements" or "when the FDA requires the manufacturer to employ certain words to convey information about its product." Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324, 332 (1996). The Fourth Circuit has likewise not cited the Riegel opinion in any subsequent cases, although device manufacturers and their counsel can undoubtedly expect far more frequent encounters with alleged parallel or incidental claims involving otherwise protected medical devices as the plaintiffs' bar seeks new ways to recover for injuries attributable to these products.

B. Warner-Lambert Co. v. Kent: Preemption of State Tort Reform Exceptions for Fraud-on-the-FDA

Drug and device companies eagerly awaited the Supreme Court's decision in Warner-Lambert Co. v. Kent, __ U.S. __, 128 S. Ct. 1168 (2008) (per curiam), which was expected to resolve a split between the Sixth and Second Circuit Courts of Appeals as to whether fraud-on-the-FDA exceptions in state tort reform statutes survived federal preemption under the FDCA and MDA. The decision in Kent arose out of Rezulin product liability litigation. At issue in the case was a Michigan tort reform statute shielding drug manufacturers from product liability claims if the drug at issue was approved by the FDA and the drug and its labeling complied with the FDA's approval at the time it left the manufacturer's control. Mich. Comp. Laws § 600.2946(5). The statute excepted from immunity, however, any drug manufacturer that intentionally withholds from or misrepresents information that is required to be submitted to the

FDA and which, if accurately disclosed, would have altered the FDA's approval of the allegedly harmful drug. Mich. Comp. Laws § 600.2946(5)(a).

In 2004, the Sixth Circuit issued an opinion in Garcia v. Wyeth-Ayerst Labs, holding that the Michigan exception was impliedly preempted by the FDCA and MDA to the extent it injected proof of fraud-on-the-FDA as a necessary element of liability under Michigan tort law. Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 966-67 (6th Cir. 2004) (relying on Buckman v. Pltf's Legal Comm., 531 U.S. 341 (2001) (holding FDCA impliedly preempts state law "fraud-on-the-FDA" claims because they conflict with the FDA's own responsibility to police fraud)).

Two years later, the Second Circuit reached the opposite conclusion in Kent (known in the lower court as Desiano v. Warner-Lambert Co.). Faced with the same Michigan statute, the Court of Appeals held that the FDCA did not preempt the immunity exception because it was not aimed at policing the FDA and because fraud-on-the-FDA merely provided an exception to an affirmative defense and did not constitute an element of the plaintiffs' product liability claims. Desiano v. Warner-Lambert Co., 467 F.3d 85 (2d Cir. 2006).

If industry insiders expected the Supreme Court to finally resolve the issue on appeal, they were sorely disappointed. In a nonprecedential, per curiam opinion, an evenly divided court affirmed the decision of the Second Circuit in Kent. Chief Justice Roberts recused himself from the case, and the opinion gives no indication of how the remaining eight justices voted or an explanation for the decision.

Despite the continued uncertainty resulting from the Court's decision, the opinion holds little impact for practitioners in our state. North Carolina's Products Liability Act, N.C. Gen. Stat. § 99B-1 et seq., does not contain a fraud-on-the-FDA provision similar to the Michigan law at issue in the Garcia and Kent cases, and the Fourth Circuit has not addressed the issue involved in those cases (although it has held, in Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 203 n.3 (4th Cir. 2001), that direct claims for fraud-on-the-FDA are preempted). Until the Supreme Court has another opportunity to answer this question on a broader scale, litigants in Fourth Circuit cases applying the law of a state providing a similar immunity exception remain free to argue either for preemption under Garcia or against it under Kent.

C. Wyeth v. Levine: Preemption of Claims for Inadequate Warning Following FDA Approval of a Drug Label

The Supreme Court's opinion in Wyeth v. Levine, 555 U.S. ___, 129 S. Ct. 1187 (2009) may be the most impactful of the three recent decisions. In Wyeth, the Court addressed the issue of whether FDA approval of drug labeling impliedly preempts state law failure to warn claims asserting that an approved label is inadequate. The Court concluded that it does not.

Unlike the MDA, the FDCA does not contain an express provision preempting state law claims against drug manufacturers. As a result, pharmaceutical companies have not historically asserted preemption defenses to state law claims based on failure to warn theories. These defenses have become increasingly more common in the last few years, however, due in part to the FDA's own recent support for preemption, particularly explicit pro-preemption language the

Agency included in a 2006 preamble to new drug labeling rules. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006); David A. Kessler and David C. Vladeck, A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims, 96 Geo. L.J. 461 (2008).

The Wyeth decision dealt with just such a defense. The plaintiff in that case, Levine, was injured by an intravenous dose of the drug Phenergan, an anti-nausea drug, administered using the IV-push method rather than the allegedly safer IV-drip method. When injected, the drug entered an artery rather than the intended vein, causing the plaintiff to develop gangrene and ultimately requiring amputation of her arm.

Levine filed suit against the drug manufacturer, Wyeth, in state court, asserting common law negligence and strict liability claims. She alleged that the drug label warning of the danger of arterial contact was defective in that it failed to specify that health care providers should administer the drug via the IV-drip method rather than the IV-push method. Wyeth moved for summary judgment on the grounds that federal law impliedly preempted Levine's state law failure to warn claims. The trial court denied Wyeth's motion and its subsequent motion for judgment as a matter of law following a jury verdict in favor of Levine. The Vermont Supreme Court affirmed, holding that the jury verdict did not conflict with FDA labeling requirements and, therefore, was not preempted.

Granting certiorari, the Supreme Court confronted the question of "whether the FDA's drug labeling judgments 'preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." Wyeth, 129 S. Ct. at 1193. Wyeth asserted two distinct and unsuccessful implied preemption arguments before the Supreme Court.

First, Wyeth argued that because of a 2008 regulatory amendment providing that CBE pre-approval labeling changes could only be made based on "newly-acquired information," the company could not simultaneously comply with its state law obligation to provide a stronger warning without violating the FDCA's approval requirement. The Court rejected this argument, holding that Wyeth could have complied simultaneously with both federal and state requirements because of an expanded definition of "newly-acquired information" that includes both new information and "new analyses of previously submitted data." Id. (citing 73 Fed. Reg. at 49604). The Court emphasized that a central premise of federal drug regulation is that the manufacturer is continually responsible for the content of its label, meaning that it must both design an adequate label and maintain the adequacy of the label as long as the drug remains on the market. As such, when the risk of gangrene and amputation from the IV-push delivery method became clear, "Wyeth had a duty to provide a warning that adequately described that risk," and the FDCA CBE process allowed Wyeth to amend its warning label before obtaining FDA approval.

In its alternative argument, Wyeth maintained that Levine's claims were preempted because they conflicted with "Congress' purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." Id. (citation omitted). The Court noted, however, that the FDCA was enacted to increase consumer protection against harmful drugs and cosmetics, and that Congress did not provide a federal remedy for consumers

harmed by unsafe products. In the majority's view, Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness; instead it apparently anticipated that consumers would avail themselves of state law claims where necessary. The Court refused to defer to the FDA's own pro-preemption views expressed in the 2006 regulatory preamble, noting that the agency pronouncement had not been subjected to comment before its inclusion in the regulations and, further, that the new interpretation conflicted with the FDA's prior recognition of the role of state tort laws as "an additional, and important, layer of consumer protection that complements FDA regulation," id., and uncovers unknown drug hazards, provides incentive to manufacturers to disclose risks, and motivates injured consumers to come forward with information.

The Wyeth decision did not negatively impact existing North Carolina or Fourth Circuit caselaw. Previous North Carolina and Fourth Circuit decisions addressed issues of preemption in the pharmaceutical context, but none addressed the exact issues before the court in Wyeth. The Wyeth decision makes it clear that the FDCA regulatory scheme is a floor, not a ceiling, and does not preempt state law claims for inadequate warnings despite the FDA's approval of a particular drug label. However, while it is now clear that simple approval of a drug label does not insulate the manufacturer from product liability claims, Wyeth left the door wide open for future cases presenting clear evidence that the FDA either considered and rejected or would not have approved labeling information that a plaintiff alleges is required for an adequate warning. See, e.g., Horne v. Novartis Pharmaceuticals Corp., 541 F. Supp. 2d 768 (W.D.N.C. 2008) (holding inadequate warning claims preempted where the FDA had already rejected a causal link for the alleged risk and such claims would create a direct conflict between requirements of state and federal law that would put the manufacturer in an impossible situation). It remains to be seen how this new rule will affect the volume of requests filed with the FDA to amend or supplement labels as drug companies seek to avoid the result in Wyeth in future cases.

III. Recent Legislative and Executive Actions to Limit Preemption

A. Legislative Action to Limit Preemption

The immunity afforded to medical device manufacturers in Riegel may be short lived. Congress is currently considering the Medical Device Safety Act of 2009, identical House and Senate bills that would, if enacted, overturn the decision by retroactively amending the MDA to prevent the preemption clause in § 360k(a) from preempting or otherwise affecting any action for damages or the liability of any person under state law. S. 540 and H.R. 1346. The bills, introduced by the late Senator Edward M. Kennedy (with North Carolina Sen. Kay Hagan among the co-sponsors) and Representative Frank Pallone, Jr., are currently being considered in committee and seem likely to pass given the current makeup of Congress. Representative Pallone, introducing the House bill just one day after release of the Wyeth opinion, explained that the bill is intended to give patients injured by medical devices the same right to legal recourse available under Wyeth for injuries from pharmaceutical products. Committee on Energy and Commerce Media Advisory, Health Leaders Introduce Legislation Reversing Supreme Court's Medical Device Decision, March 5, 2009, available at: http://energycommerce.house.gov/ (last visited on June 11, 2009).

B. Executive Action to Limit Preemption

The federal executive branch is equally poised to limit the availability of regulatory preemption defenses across the board. On May 20, 2009, President Obama issued a presidential memorandum outlining the general policy of the current administration "that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption" and laying out rules for the future inclusion of preemption statements in federal regulations. Presidential Memorandum dated May 20, 2009, available at: www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/ (last visited May 31, 2009). The President also directed the heads of departments and agencies to scour federal regulatory publications for preemption statements issued within the past ten years—a time period presumably chosen to encompass any enactments by the Bush Administration—to "decide whether such statements or provisions are justified under applicable legal principles governing preemption," and to remove those statements if necessary. Id.

While the President stopped short of directing the removal of all preemption regulations and statements adopted by the previous administration, it would be safe to assume that the presidential memorandum will result in a general weakening of the bases for regulatory preemption arguments in a variety of contexts. The effects of this executive action should be limited in the drug and medical device context, however, as Riegel turned on an express *statutory* preemption clause and Wyeth already dispelled most reliance on preemption language adopted by the FDA in recent drug labeling rules.

In fact, the FDA had already begun reevaluating its position on preemption in light of the Supreme Court's skepticism and holding in Wyeth. For example, on April 28, 2009, the Solicitor General submitted a letter to the Third Circuit in the case of Colacicco v. Apotex, Inc., No. 06-3107 (3rd Cir.), withdrawing the FDA's previously filed amicus brief in support of the defendant pharmaceutical company and stating that the FDA "has not yet conducted the sort of reexamination of various preemption issues following the Supreme Court's decision in Wyeth that would be necessary to inform a position of the United States in this case." See James M. Beck and Mark Herrman, Solicitor General's Letter in Colacicco on Remand, Drug and Device Law, April 28, 2009, available at: druganddevicelaw.blogspot.com/2009/04/solicitor-generals-letter-in-colacicco.html (last visited on August 27, 2009).

IV. Conclusion

Given the absolute nature of the preemption defense, it is not surprising that the issue sparks vigorous debate even among the jurists charged with construing it. Drug and device manufacturers and their counsel have ridden the preemption roller coaster through good times and bad over the last few years, but they have not yet reached the end of the line. Wyeth severely restricted implied preemption arguments; nevertheless, preemption remains a viable defense if the manufacturer can prove that the FDA considered and rejected the allegedly necessary improvements proposed by the plaintiff. Riegel likewise recognized broad express preemption for Class III devices receiving premarket approval, but did not foreclose the option of parallel state claims alleging violation of the FDA rules themselves. The scope and proper

resolution of these remaining issues will be left to the district and circuit courts over the coming months and years, and should provide plenty of opportunities for both sides of the debate to continue to shape the law in this area.

The break in the Supreme Court action may not last long, either. Although the Supreme Court has not yet added any new preemption cases to its docket for the upcoming 2009-2010 term, it is currently considering whether to grant certiorari in American Home Products Corp. v. Ferrari, No. 08-1120, a decision out of the Supreme Court of Georgia that would require the Court to determine whether the National Childhood Vaccine Injury Act of 1986 preempts state law design defect claims alleging that the manufacturer should have employed an allegedly safer design than was approved by the FDA. The briefs are in from the parties, and on June 8, 2009, the Court issued an order inviting the Solicitor General to file a brief in the case expressing the views of the United States. There is good reason to believe that the Court will take the case if the government encourages it to do so.

Even Congress and the Obama Administration may soon be poised to contribute in their own way. Industry practitioners will be tracking the progress of the Medical Device Safety Act with interest and should also keep a wary eye out for potential administrative action scaling back the regulatory bases for defense preemption arguments. Regardless of how these initiatives pan out, challenges to the federal preemption defense in this field are not disappearing anytime soon.