“U.S. Consumer Protection: Striking a Balance Between the FDA Approval Process and State Tort Law Claims Through the Medical Device Safety Act of 2009”

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As a matter of public policy, Congress wants to protect consumers of pharmaceuticals and medical devices.[1] In seeking to accomplish this objective, a balance is struck between the Food and Drug Administration (FDA) using scientific expertise when making public health determinations[2] and judges and jurors protecting the individuals through state tort liability actions.[3] “State law serves a compensatory function distinct from federal regulation.”[4] In seeking to determine if claims brought against manufacturers of prescription drugs and medical devices based on state tort law claims can be preempted by federal law, the U.S. Supreme Court has reached different conclusions. In Wyeth v. Levine, the Court held that the Federal Food, Drug, and Cosmetic Act (FDCA) did not preempt state tort law claims against pharmaceutical companies.[5] Riegel v. Medtronic, decided just a year earlier, reached the opposite conclusion for medical device companies.[6]

The purpose of the article is to discuss how the Medical Device Safety Act of 2009 reconciles the divergent holdings in these cases. Part I of the article addresses the types of preemption and compares and contrasts the decisions in Wyeth and Riegel. Part II concludes that congressional initiatives in light of the Supreme Court’s rulings would provide a clear legislative intent of protecting consumers of pharmaceuticals and medical devices by having the FDCA and state tort claims work in tandem.

Preemption in Relation to Wyeth and Riegel

Just as a court’s analysis of a contract begins with the four corners of the document, the scope of federal preemption analysis must start with statutory text. Interpretation of the
language, however, does not occur in a contextual vacuum. [7] Rather, it is informed by two presumptions about the nature of preemption. First, because Congress does not “cavalierly pre-empt state-law causes of action” in all preemption cases, the historic police powers of states were not to be superseded by federal act unless that was the clear and manifest purpose of Congress. [8] Second, the understanding of the preemption statute’s scope must reside primarily on congressional purpose. [9]

Throughout our nation’s history, numerous states have exercised their police powers to protect the health and safety of their citizens. [10] “States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.” [11] Both Wyeth and Riegel addressed preemption in relation to the FDCA (albeit different provisions) and the presumption of Congress to respect the “historic presence of state law” while “not rely[ing] on the absence of federal regulation.” [12]

In Wyeth, the issue was whether federal law preempted the plaintiff’s claim that the drug’s label did not contain an adequate warning about using a particular method of administration. [13] The Court, in order to determine the congressional purpose, reviewed the history of federal drug and drug labeling regulations. In 1962, when the FDA’s powers were enlarged to “protect public health” and “assure the safety, effectiveness, and reliability of drugs,” Congress carefully preserved state law. [14] Even in the case of implied (field) preemption, which is what the Court faced in Wyeth, the presumption against preemption does not apply. [15]

In Riegel, the issue was whether the preemption clause in the Medical Device Amendments of 1976 (MDA) barred common-law claims challenging the safety and effectiveness of a medical device when pre-market approval had been granted by the FDA. [16] The Court considered the regulatory history of medical device legislation and how the Dalkon Shield contributed to Congress addressing the “inability of the common-law tort system to manage the risks associated with dangerous devices.” [17] Unlike the provision regulating drug labels, “the MDA includes an express pre-emption provision.” [18] Congress did, however, provide the FDA with the ability to carve out some state and local requirements from preemption. [19] Still, the Court reached the conclusion that the “failure to warn” negligence case would be akin to the state court jury writing a new requirement that would directly conflict with a federal statute providing that the FDA’s warning was the exclusive warning for the pacemaker at issue. [20]

But, in her dissent, Justice Ginsburg raised the question of whether there was a presumption against finding “preemption” in Supremacy Clause cases. [21] The conclusion was that the legislative history of laws regulating drugs and medical devices, like the
FDCA and the MDA “were all enacted with common-law personal injury litigation over defective products a prominent part of the legal landscape.”[22] “In sum, state premarket regulation of medical devices, not any design to suppress tort suits, accounts for Congress’ inclusion of a preemption clause in the MDA; no such clause figures in earlier federal laws regulating drugs and additives, for States had not installed comparable control regimes in those areas.”[23]

**Congressional Attempts at Unifying Wyeth and Riegel**

In order to answer the preemption question that received conflicting responses in *Wyeth* and *Riegel*, the 111th Congress introduced the “Medical Device Safety Act of 2009.”[24] The Act reconciles the recent Supreme Court holdings by recognizing the value in utilizing both FDA regulations and state tort laws to ensure the safety of medical devices.[25] Basically, the Act would allow injured patients to hold negligent medical device manufacturers liable for damages utilizing state courts and state laws for product-related deaths and injuries, as had been the case prior to *Riegel*.[26]

The Act seems to be consistent with the legislative history and judicial precedent of supporting the continued rights of state regulation of product liability law. The product liability laws of individual states enable state citizens to hold manufacturers accountable for negligently caused injuries. State laws serve two main purposes: first, to compensate the injured consumer; and second, to impart a financial incentive on the manufacturer to make its product as safe as possible or recall the product even if the product or its label is FDA approved.[27]

In sum, this legislation clarifies that state common-law negligence claims against medical device manufacturers were not meant to be preempted. To the contrary, state tort law systems are meant to work in tandem with the different facets of the FDCA to ensure the health and safety of medical device and pharmaceutical consumers.

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[1] Wyeth v. Levine, 129 S. Ct. 1187 (2009) (identifying the “purpose of Congress” by reviewing the historic federal regulation in drugs and drug labeling: 1906—Federal Food and Drugs Act (ch. 3915, 34 Stat. 768) – purpose was to protect consumers from the manufacture or interstate shipment of adulterated or misbranded drugs. Supplemented the protection for consumers already provided by state regulation and common law liability. 1930’s—Federal Food, Drug, and Cosmetic Act (FDCA) (Ch. 675, 52 Stat. 1040) (as amended 21 U.S.C. § 301)—most substantial impact was the requirement of pre-market approval of new drugs. It required every manufacturer to submit a new drug application, including reports of investigations and specimens of proposed labeling to the FDA for review).


[4] Id.

[5] Id.

[6] Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008) (holding in an 8-1 decision that a “failure to warn” negligence case should be struck down on the theory that a state court jury would be writing a new “requirement” that would directly conflict with a federal statute providing that the FDA warning was exclusive); Federal Food, Drug, and Cosmetic Act, § 513(a)(1)(A, B, C) as amended 21 U.S.C.A. § 360c(a)(1)(A, B, C), § 360(k) (providing the FDA with the option of concluding that a device is “substantially equivalent” to a preexisting device; therefore, allowing marketing without further regulatory analysis).

[7] Lohr v. Medtronic, Inc., 518 U.S. 470, 485 (1996) (deciding whether state tort law claims of negligence and strict liability against a manufacturer for a pacemaker, which was a Class III medical device that had received § 510(k) approval, was not preempted by the Medical Device Amendments (MDA) because the MDA does not preempt state or local requirements that are equal to or substantially equivalent to the language of the requirements imposed by federal law. In fact, common-law tort claims fills the void of addressing safety because the § 510(k) process language is focused on equivalence).

[8] Id.


[13] Id. at 1193-1194.

[14] Id. at 1196 (adding a saving clause indicating that state law would only be invalid upon a “direct and positive conflict” with the FDCA).


[16] Riegel, 128 S. Ct. at 1002.

[17] Riegel, 128 S. Ct. at 1003-1004 (responding to the differences in state regulatory measures governing medical devices and the proliferation and failure of numerous medical devices, Congress passed the MDA, 21 U.S.C. §360c et seq. The regime established different levels of oversight for medical devices based on the risks presented. Classifications were designated as Class I (lowest level of oversight), Class II (requires "special controls" such as performance standards and postmarket surveillance measures (§360(c)(a)(1)(B)), Class III (highest level of oversight, allowed for grandfathering already existing devices and relief of pre-market approval on "substantially equivalent" submitted devices.(§§360c(f)(1), 360e(b)(1)).

[18] Medical Device Amendments of 1976 (MDA), 21 U.S.C. §360c et seq.) (containing two parts, (a) and (b). Part (a) prevented States or political subdivisions from establishing any requirement that “(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) 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.” §360k(a). Part (b) created an exception which permits the FDA to exempt some state and local requirements from pre-emption).


[21] Id. at 3-4.

[22] Riegel, 128 S. Ct. at 1018 (Ginsburg, J., dissenting).

[23] Id..

[24] Medical Device Safety Act of 2009, H.R. 1346, S. 540, 111th Cong. (2009) (reintroducing what was previously introduced in the 110th Congress as H.R. 6381, which never made it to a vote). "Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, SECTION 1. SHORT TITLE. This Act may be cited as the 'Medical Device Safety Act of 2009'. SEC. 2. LIABILITY UNDER STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES. (a) Amendment- Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) is amended by adding at the end the following:'(c) No Effect on Liability Under State Law- Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.' (b) Effective Date; Applicability- The amendment made by subsection (a) shall--(1) take effect as if included in the enactment of the Medical Device Amendments of 1976 (Public Law 94-295); and (2) apply to any civil action pending or filed on or after the date of enactment of this Act."


[25] Id.


[27] Id.