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Preemption of State Products Liability-Based Claims in Medical Device and Drug Labeling Cases in the *Riegel v. Medtronic, Inc./Wyeth v. Levine* Interlude

By

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I. Scope of Presentation. This presentation is designed to familiarize the listener with basic preemption principles applicable in medical device and drug labeling cases following *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), and in advance of *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), cert. granted 128 S. Ct. 1118 (2008) (No. 06-1249).

II. Relevant Principles.

A. Preemption. The Supremacy Clause of the federal Constitution, U.S. Const. art. VI, cl. 2, is the basis for the doctrine of preemption, according to which “state law that conflicts with federal law is ‘without effect,’” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). The relevant framework for determining whether a federal statute preempts state law was set forth in *Cipollone*:

Congress’ intent may be explicitly stated in the statute’s language or implicitly contained in its structure and purpose. In the absence of an express congressional command, state law is preempted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.

Id. (quotations and internal citations omitted). Without an express intent to preempt state law, there is a presumption against preemption. Medtronic v. Lohr, 518 U.S. 470, 485 (1996). The presumption against preemption has additional force when there has been a “long history of tort litigation” in the area of state common law at issue. Bates v. Dow Agrosiences LLC, 544 U.S. 431, 449 (2005).

Distilled, there are three kinds of preemption: (1) express, (2) field, and (3) conflict. A party attempting to demonstrate a conflict between a federal standard and a state standard must show either that “it is impossible for a private party to comply with both state and federal requirements” or that the state requirement “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” Freightliner Corp. v. Myrick, 541 U.S. 280 (1995). To demonstrate that a state requirement poses an obstacle to the purposes and objectives of Congress, courts must examine whether the state law requirement would upset the balance struck by a deliberate policy decision embodied in the federal requirement. See Geier v. Am. Honda Motor Co., 529 U.S. 861, 864-66, 874-75 (2000).

- B. The Food, Drug, and Cosmetic Act of 1938, as amended, 21 U.S.C. §§ 301-399 (2006) (FDCA).** The federal Food, Drug, and Cosmetic Act replaced the Pure Food and Drug Act of 1906 and imbued the Food and Drug Administration (FDA) with power to regulate the safety of food, drugs, and cosmetics. The FDCA came into being, in part, because of public backlash following the distribution of a drug known as elixir sulfanilamide, which was designed to treat strep in children, but actually contained a toxic chemical closely related to antifreeze. The FDCA was also promulgated to curb “quack” products promising to remedy medical ailments but often did more harm than good.

Among other things, the FDCA brought cosmetics and drugs under the guise of federal statutes and regulations, required that drugs be labeled with adequate directions for safe use, and mandated premarket approval (PMA) for all new drugs. The PMA process required manufacturers to demonstrate to the FDA that the proposed drugs were safe before they were sold.

At this point, medical devices were not subject to the PMA requirement, and the statute was silent concerning the interaction between the FDCA and existing state laws.

- C. The Medical Device Amendments, 21 U.S.C. § 360c et seq. (MDA), and the Premarket Approval Process for Medical Devices (A Lohr/Riegel Preview).** Thousands of tort claims resulted from the failure of the Dalkon Shield intrauterine device in the early 1970s. Several states thereafter began

to require premarket approval for certain medical devices. Congress eventually enacted the Medical Device Amendments to the FDCA in 1976, which set forth a detailed federal scheme designed to replace (in part) and supplement (in part) existing state regulations.

Regarding preemption, the MDA contains an express preemption provision:

Except as provided in subsection (b) of this section, 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—

- (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.

21 U.S.C. § 360k(a). The referenced subsection (b) permits the FDA to exempt some state and local requirements from preemption. Id. § 360k(b).

The MDA also established different levels of oversight for medical devices. Class I devices, subject to the lowest level of oversight, must comply with “general controls,” such as labeling requirements. Id. § 360c(a)(1)(A). Class I devices typically pose no unreasonable risk of illness or injury. Class II devices must comply with “special controls” such as performance standards and post-market surveillance measures. Id. § 360c(a)(1)(B). Class II devices are potentially more harmful than Class I devices, but can be marketed without advance approval.

Class III devices receive the most scrutiny. A device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurances of safety and effectiveness and if the device is “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” or “presents a potential unreasonable risk of illness or injury.” Id. § 360c(a)(1)(C)(ii). Following the MDA, Class III devices became subject to a rigorous PMA procedure, outlined below.

The MDA contained a “grandfathering” provision that permitted pre-1976 devices to remain on the market while the FDA promulgated its PMA regulations. Id. §§ 360c(f)(1), 360e(b)(1). To prevent grandfathered device manufacturers from monopolizing the market while new devices obtained PMA, the MDA permitted devices that are “substantially equivalent” to pre-1976 devices to avoid the PMA process. Id. §§ 360c(f)(1)(A), 360e(b)(1)(B).

The review process for determining whether a device is a substantial equivalent is known as the section 510(k) review process. See id. § 360(k). Through this process, a manufacturer intending to market a new device substantially equivalent to a pre-1976 device must submit a “premarket” notification”; if the FDA determines the device is substantially equivalent to a pre-existing device, the device can be marketed without further regulatory analysis. This procedure consumes approximately 20 hours of regulators’ time.

If a new device is deemed to be substantially equivalent to a pre-1976 device, the new device is subject only to generally applicable federal regulations applicable to all medical devices.

Most devices enter the market through the section 510(k) procedure: in 2005, the FDA authorized marketing of 3148 devices under section 510(k), but granted PMA to only 32 devices.

PMA for medical devices is rigorous. A manufacturer must submit reports of studies and investigations of the device’s safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device’s components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components the FDA might require; and a sample label. Id. § 360e(c)(1). The FDA may refer the device to a panel of outside experts, and might require the manufacturer to submit additional information. Id. §§ 360c, 360e(c)(1)(G); 21 C.F.R. § 814.44(a). Reviewing the typical PMA application requires approximately 1200 hours.

PMA is granted only if the FDA determines that there is a “reasonable assurance” of the device’s “safety and effectiveness” based on the uses proposed in the device’s label. 21 U.S.C. §360e(d). To arrive at such a reasonable assurance, the FDA must, among other things, “weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.” Id. § 360c(a)(2)(C). Devices that are not always safe may thus be approved if they offer a significant potential benefit.

PMA also includes a detailed review of the device’s labeling. The FDA reviews proposed language for safety and effectiveness, and will only approve a label if the label is neither false nor misleading. Id. § 360c(a)(2)(B), 360e(d)(1)(A).

After completing the PMA process, the FDA may grant or deny an application, id. § 360e(d)(1)(A)(i)-(ii), or condition approval on adherence to performance standards designed to reduce risks associated with using the device, 21 C.F.R. § 861.1(b)(3), restrictions on sale or distribution, or compliance with other requirements the FDA may promulgate, 28 U.S.C. § 360j(e)(1); 21 C.F.R. § 814.82. If approval is not possible, the FDA may draft an “approvable letter,” which indicates that the device could be approved if the applicant submitted information or agreed to certain restrictions or conditions. 21 C.F.R. § 814.44(e). The FDA may also draft a “not approvable letter” that lists grounds for denial and suggests measures the applicant could take to earn approval. Id. § 814.44(f).

After obtaining PMA, the MDA forbids changing the design, manufacturing processes, labeling, or any other attribute that would affect the safety or effectiveness of the device. 21 U.S.C. § 360e(d)(6)(A)(i). To obtain a change, the manufacturer must submit, and the FDA must approve, an application for supplemental premarket approval that contains review procedures as rigorous as the PMA itself. Id. § 360e(d)(6); 21 C.F.R. § 814.39(c).

Devices obtaining PMA also remain subject to reporting requirements. See 21 U.S.C. § 360i. These requirements include notifying the FDA of new clinical investigations or scientific studies concerning the device or scientific studies concerning the device which the applicant knows of or should be reasonably aware of, 21 C.F.R. § 814.84(b)(2), and to report incidents in which the device caused or may have contributed to death or serious injury, or malfunctioned in such a manner that the device could have caused or contributed to death or serious injury if it recurred, id. § 803.50(a). The FDA may suspend or withdraw PMA based on this data if the FDA decides the device is unsafe or ineffective. 21 U.S.C. § 360e(e)(1).

- D. Regulations Informing Drug Labeling Requirements, The Kefauver-Harris Amendments of 1962, Pub. L. No. 87-781, and Purported Preemption of State Law Claims in Label Defect-Based Cases (A Wyeth Preview).** In the earliest days of the FDCA, the FDA evaluated drugs for safety, only. In addition to the MDA, among the FDCA’s more significant revisions occurred in 1962 with the passage of the Kefauver-Harris Amendments. The Kefauver-Harris Amendments were passed in response to the distribution of thalidomide, a sedative which was never approved for sale in the United States but which, when administered, produced deformities in newborns. Among other things, the Kefauver-Harris Amendments created a standard that required a review of the efficacy and safety of a drug before it could be marketed, required the FDA to re-assess the efficacy of all drugs introduced since 1938, required tighter agency control over drug trials, and

established standards known as Good Manufacturing Processes for drug manufacturers.

Before distributing a prescription drug, a manufacturer must submit a New Drug Application (NDA) to the FDA. 21 U.S.C. § 355(a). The FDA must approve the NDA unless it fails to meet certain criteria, including whether test results and other information establish the drug is “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof,” whether there is “substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof,” and whether, “based on a fair evaluation of all material facts, such labeling is false or misleading.” *Id.* § 355(d). The FDA’s complex labeling regulations are set forth in considerable detail in the Code of Federal Regulations. *See* 21 C.F.R. part 201.

Once a drug and its label have been approved, changes to the label typically require the submission and FDA approval of a Supplemental NDA. *Id.* § 314.70(b)(2)(v)(A). Considerable debate surrounds the subject of whether a manufacturer can—or must—alter the label in certain circumstances without FDA approval.

For example, one regulation provides that approved drug “labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug[.]” *Id.* § 201.80(e). A further regulation provides:

- (6) The [FDA] may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change. These changes include, but are not limited to:
 - ...
 - (iii) Changes in the labeling . . . to accomplish any of the following:
 - (A) To add or strengthen a contraindication, warning, precaution, or adverse reaction;
 - ...
 - (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product[.]

21 C.F.R. § 315.70(c). One of the principal issues surrounding these regulations is whether they grant to manufacturers the power to unilaterally strengthen warnings.

The Kefauver-Harris Amendments also contained an express preemption clause, which reads as follows: “Nothing in the amendments made by this Act to the [FDCA] shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law.” Pub. L. No. 87-781, § 202.

For several years, the FDA never suggested that state law-based product liability claims created a “direct and positive” conflict. In fact, the FDA suggested the opposite in 1979 and 1998. *See* 63 Fed. Reg. 66378, 66384 (1998); 44 Fed. Reg. 37434, 37437 (1979). The FDA also noted that a regulation promulgated in 2000 designed to require a “Highlights” section on drug labels did not preempt state laws. 65 Fed. Reg. 81082, 81103 (2000). However, in new regulations proposed 2006, the FDA claimed that in certain circumstances the FDA’s approval of a drug label could preempt state law tort claims based on a failure to warn. Specifically, the FDA stated that such a conflict existed when a state law “purport[ed] to compel a [manufacturer] to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated . . . [or if a state requirement] purport[ed] to preclude a [manufacturer] from including in labeling or advertising a statement that is included in prescription drug labeling.” 71 Fed. Reg. 3922, 3935 (2006).

III. Medtronic v. Lohr, 518 U.S. 470 (1996).

- A.** Medtronic, Inc., manufactured a pacemaker equipped with Model 4011 pacemaker leads. Plaintiffs, husband and wife, sued Medtronic alleging violations of Florida common law principles after the pacemaker lead failed. Plaintiffs alleged Medtronic was negligent because it used defective materials in the lead and failed to warn or properly instruct the plaintiff or her physicians of the tendency of the pacemaker to fail. Plaintiffs also brought a strict liability claim, contending the pacemaker was in a defective condition and was unreasonably dangerous at the time of sale. Medtronic claimed Plaintiffs’ claims were preempted by section 360k(a).

- B.** The Court noted that Medtronic took advantage of the section 510(k) expedited approval process by claiming the pacemaker was substantially equivalent to an existing product. The FDA agreed, and notified Medtronic that it could market the device subject only to the general control provisions of the FDCA. The FDA cautioned that its approval should not be construed as an endorsement of the pacemaker’s safety. As a result, the principal question

in Lohr was whether the device's approval pursuant to section 510(k) required preemption of Plaintiffs' common law claims under section 360k(a).

C. A majority of the Court assumed that section 360k(a) did not preempt all common law claims, but instead analyzed whether that section preempted the specific claims advanced by Plaintiffs. Plaintiffs first argued that their negligent design claims were not preempted because the section 510(k) premarket notification process imposed no federal "requirement" on the design of the pacemaker. Second, Plaintiffs contended that even if the FDA's general rules are "requirements," those rules preempt state requirements different from Plaintiffs' claims because section 360k(a) does not preempt state rules that duplicate federal rules. Finally, Plaintiffs argued a State's decision to impose general common law duties upon a manufacturer does not result in the imposition of a requirement upon a manufacturer "with respect to a device."

1. With respect to Plaintiffs' negligence design claim, Medtronic argued the FDA's determination that the pacemaker was "substantially equivalent" to an existing device and the FDA's ability to exclude the device from the market after approval resulted in a specific, continuing, and federally-enforceable design requirement. Rejecting this argument, the Court noted that the section 510(k) process focuses on equivalence, not safety. Consequently, the section 510(k) approval process does little to protect the public: a finding of substantial equivalence merely meant that a post-1976 device was equivalent to a pre-1976 device. The purpose of section 510(k) was to afford post-1976 manufacturers the ability to compete with pre-1976 manufacturers. This was why the FDA warned Medtronic that its finding of substantial equivalence did not mean the pacemaker was necessarily safe, especially because Medtronic merely had to comply with general regulations applicable to all medical devices.

The goal of section 510(k) was not to intensely regulate safety and efficacy; the goal was to maintain the status quo as it existed upon passage of the MDA, which, at that time meant that a manufacturer would need to defend against state law-based negligent design claims.

2. The Court also addressed Plaintiffs' argument that any allegations that Medtronic violated an FDA regulation which were also based on state law principles were not preempted by section 360k(a). The Court noted that nothing in section 360k(a) denied Florida the right to provide traditional damages remedies for violations of common law duties when those duties parallel federal requirements. The requirement that a plaintiff prove more elements to prevail on a state

law-based claim than needed to demonstrate a violation of a federal regulation (e.g., a plaintiff might need to demonstrate that the product created an unreasonable hazard for its users) only narrowed the scope of any state requirements. Even though the state law-based claims would technically impose “different” requirements from federal requirements, the Court elected to preserve traditional state law remedies.

3. Finally, the Court considered whether allowing Plaintiffs to pursue manufacturing and labeling defect claims against Medtronic would pose an obstacle to enforcing certain general federal regulations. Specifically, the Court analyzed whether allowing a state remedy would hinder application of a regulation requiring device labels to include information for use, relevant hazards, contraindications, side effects, and precautions. The Court also considered whether allowing manufacturing and labeling defect claims to proceed would encumber a separate regulation requiring compliance with Good Manufacturing Practices.

Plaintiffs contended that while these regulations existed, their general nature did not require preemption of claims alleging that a manufacturer did not comply with other duties under state common law. Plaintiffs noted that section 360k(a)(1) requires that a federal requirement be “applicable to the device” in question to have any preemptive effect. Plaintiffs argued general labeling regulations apply to a host of devices, and did not apply to any specific device. Moreover, Plaintiffs noted, under section 360k(a)(2), the supposedly preempted state standards must apply “with respect to a device” and then only if the requirement “relates to the safety or effectiveness of the device” does preemption occur.

Turning to the FDA’s interpretation of the MDA through its own regulations, the Court noted that 21 C.F.R. section 808.1(d) provided that state requirements are preempted only when the FDA established “specific counterpart regulations . . . or specific requirements applicable to a particular device.” The same regulation indicated that the MDA was not designed to preempt “State or local requirements of general applicability where the purpose of the requirement relates either to products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices.” The regulations identified general electrical codes and the Uniform Commercial Code warranty of fitness as examples of rules that would not be preempted. The Court held that while this language does not preclude “general” federal regulations from ever preempting

state requirements, or “general” state requirements from ever being preempted, the FDA’s regulations animate the MDA’s intent that preemption only occur where a particular state requirement threatens to interfere with a specific federal requirement applicable to a particular device.

Because state requirements must be “with respect to” medical devices and “different from, or in addition to” federal requirements, and must also relate “to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device,” and because the FDA’s regulations provide that state requirements of “general applicability” are not preempted unless they have “the effect of establishing a substantive requirement for a specific device,” the further requirement that preemption occur only where a state has enacted a “specific counterpart regulation” that is “specific” to a “particular” device necessitated a comparison between the federal requirement and the state requirement to determine if both fell within the intended preemptive scope of the statute and regulations.

Applied, the Court concluded Plaintiffs’ claims survived. The Court observed that the generality of the FDA’s labeling and manufacturing requirements was unlike situations where the federal government weighed competing interests to reach a policy decision that was expressed in a specific regulation. Instead, the applicable general federal rules reflected generic concerns about devices generally, not specific concerns about a specific device. Additionally, generally applicable state common law requirements were not developed “with respect to” medical devices. As a result, state common law standards did not represent the kinds of requirements the FDA feared would impede federal regulators’ ability to implement and enforce federal regulations.

IV. Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008).

- A.** Medtronic, Inc. manufactured a device known as an Evergreen Balloon Catheter, a Class III medical device that received PMA from the FDA. Changes to the device’s label received supplemental approval on two separate occasions. The device was implanted into Charles Riegel during surgery performed on his heart. His physician inserted the device into his coronary artery to dilate the artery even though the device’s labeling stated that use was contraindicated for patients like Mr. Riegel. The label also warned that the device should not be inflated beyond its burst pressure of eight atmospheres. On the fifth inflation to a pressure of ten atmospheres, the device ruptured.

Charles and his wife sued Medtronic in federal court in New York, alleging the device was designed, labeled, and manufactured in a manner that violated New York common law. The Supreme Court considered whether section 360k preempted Plaintiffs' claims.

The Court began by observing if Plaintiffs' claims were to be preempted, there must (1) be a federal requirement applicable to the device, and (2) be a state requirement applicable to the device that imposed different requirements or additional requirements.

- B.** With respect to the first prong, the Court observed that in Lohr, it had interpreted section 360k in a manner “substantially informed” by the FDA regulation found at 21 C.F.R. section 808.1(d). Recalling, section 808.1(d) indicates that state requirements are only preempted when the FDA has established specific counterpart regulations or there are other specific requirements applicable to the device. As a result, the Lohr Court held that federal manufacturing and labeling requirements which were generally applicable did not preempt common law claims of negligence and strict liability because the requirements were not specific to the device, but instead reflected generic concerns about device regulation generally. The Lohr Court held that even though the section 510(k) approval process was device specific, it imposed a qualification for an exemption rather than an positive “requirement.” The section 510(k) process focused on equivalence, not safety.

In contrast, the Riegel Court held that the PMA process—unlike the section 510(k) process—did impose requirements. The Court noted that PMA, unlike generic labeling requirements, is device specific and results from an intensive review of the device's safety: while devices passing into the market through section 510(k) are never reviewed for safety or efficacy, PMA occurred only after the FDA was assured of the device's safety and efficacy. Additionally, the FDA required a device that completed the PMA process to be made with nearly no deviations from the specifications in the PMA application. Compliance with the PMA process therefore constituted a requirement.

- C.** The more difficult question was whether the state law claims brought by Plaintiffs would impose requirements “different from, or in addition to” federal requirements related to the catheter and that “related to the safety or effectiveness of the device or other matter included in a requirement applicable to the device.”
- 1.** The Riegel Court affirmed the holding from Lohr that common law negligence and strict liability claims imposed state requirements. The

Court observed that common law liability is premised on the existence of a legal duty, and a tort judgment established the violation of a state law obligation. Requiring a medical device to be safer—and therefore less effective—to comply with state tort law principles disrupted the federal scheme. As a result, negligence and strict liability claims were preempted by section 360k(a).

2. The Court also rejected Plaintiffs' contention that the duties underlying negligence, strict liability, and implied warranty claims are not requirements "with respect to devices." This was so because Plaintiffs' claims depended on New York continuing in effect general tort duties "with respect to" the catheter. There was no provision in the MDA that suggested the preempted state requirement must only apply to the device.

To reach this conclusion, the Court rejected Plaintiffs' argument that an FDA regulation required survival of their claims. Recalling, 21 C.F.R. section 808.1(d) provides that the MDA's preemption language does not extend to "[s]tate 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 electric codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." The Court noted that the FDA had interpreted this regulation to exclude from preemption those requirements that relate incidentally to medical devices; general tort duties of care—unlike fire codes—directly regulate the device itself. Suspicious of this interpretation, the Court noted that general requirements imposed by the UCC or electrical codes could also regulate the device itself. However, elsewhere in the same regulation, the Court located a provision establishing that the MDA contained a "general rule" preempting state duties "having the force and effect of law (whether established by statute, ordinance, regulation, or court decision)." The Court was aware of no other duties established by court decision other than common law duties, and was aware of no common law duties that related specifically to medical devices.

The Court further noted regulations holding that adulteration and misbranding claims are preempted if they have the effect of establishing a substantive requirement for a specific device that is different from or in addition to a federal requirement. The Court suggested that the MDA would therefore preempt a jury determination that FDA-approved labeling for a Class III medical

device violated a state common law duty that required additional labels.

D. While Plaintiffs' claims were preempted, the Court noted that section 360k does not prevent a State from creating a damages remedy for claims premised on a violation of the FDA's own regulations. And importantly, the Court did not resolve Plaintiffs' argument that section 360k does not preempt state duties that are "parallel" to federal regulations but which do not add to those regulations.

V. **Warner-Lambert Co. v. Kent, 128 S. Ct. 1168 (2008)**. In Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), the Supreme Court held that state law claims alleging a manufacturer made fraudulent representations to the FDA were impliedly preempted by the FDCA. In Warner-Lambert, the Court considered whether a state law-based product liability statute that created a "safe harbor" from liability for FDA-approved drugs but carved out an exception for cases where the approval was obtained through fraud was also preempted. The Second Circuit Court of Appeals held that Buckman applied only to claims based on fraud and did not extend to state statutes in which the fraud on the FDA was merely part of the exception to a product liability claim rather than an element of the claim. The Supreme Court affirmed by an equally divided vote, leaving the issue for resolution at a future term.

VI. **Post-Riegel Preemption Cases Involving Medical Devices**.

A. **Stevens v. Pacesetter, Inc., No. 3:07-cv-3812, 2008 WL 2637417 (D.S.C. Apr. 1, 2008)**. Summary dismissal of Plaintiffs' claims to the extent the claims were premised on standards contrary to or in addition to the design, labeling, warning, and other standards and requirements imposed as a result of the PMA of the subject device.

B. **Adkins v. Cytec Corp., No. 4:07CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008)**. Cytec Corporation manufactured a device known as the NovaSure. During the Plaintiff's surgery, a Cytec representative was in the operating room advising the physician regarding the tests needed to determine if the device would be harmful. The tests indicated the device would be safe. Following injuries sustained during the procedure, Plaintiff sued Cytec, alleging breach of implied warranty of merchantability, breach of express warranty, negligence through inadequate design, and negligent warnings or instruction of the surgeon by Cytec's representative.

NovaSure is a Class III medical device that received PMA from the FDA. The Court ruled that because the FDA determined the design, manufacturing process, and labeling of the device was reasonably safe, a negligence finding under state common law would impose requirements different from those

imposed by the FDA. As a result, claims challenging the safety and effectiveness of the NovaSure were preempted.

The Court also concluded that the MDA did not preempt Plaintiff's claims against the Cytex representative, but concluded the claim was inadequately pled.

- C. **Heisner v. Genzyme Corp., No. 08-C-593, 2008 WL 2940811 (N.D. Ill. July 25, 2008)**. Genzyme Corporation manufactured and sold an adhesion barrier called Seprafilm that was installed in Plaintiff's wife. Plaintiff claimed his wife died as a proximate cause of the device's failure. Plaintiff sued Genzyme for various violations of Illinois and Massachusetts state laws. Specifically, Plaintiff brought negligence, breach of express and implied warranty, and strict liability claims founded upon the belief that the product was unreasonably dangerous.

Genzyme requested—and received—judicial notice that Seprafilm was a Class III device approved by the FDA pursuant to the PMA.

Applying Riegel, the Court noted that in the case before it, like Riegel, the Plaintiff made claims of strict liability, breach of implied warranty, and negligence. However, the Court noted that the Riegel Court expressed reserved the question of whether “parallel” claims were preempted, and did not address the compatibility of FDCA preemption and state law claims based on post-approval reporting requirements.

As a result, the Court found “some possibility” that the Seprafilm's failure—if any—“might” be attributed to Genzyme's negligence in a way that did not conflict with the FDA's requirements. Consequently, the Court held, to the extent Plaintiff's allegations were concerned not with the nature of Seprafilm as approved by the FDA, but rather with Genzyme's action or inaction to take part in the PMA process or implement its results, Plaintiff could satisfy the parallel claim exception to preemption.

However, as the Complaint was pled, there was no way for the Court to determine whether the Plaintiff's claims were based on requirements that were parallel to the FDA's requirements. This was so because every claim brought by Plaintiff relied directly or indirectly on a “defect” in Seprafilm. If the alleged defect or defects were intrinsic to the product as approved by the FDA, any finding of liability would almost certainly impose additional and/or different requirements upon Genzyme. Plaintiff correctly noted, though, that all Class III requirements are subject to annual reporting requirements after receiving PMA, which must identify all changes made to the device and summarize unpublished data from clinical investigations or laboratory studies or reports in scientific literature that reasonably should be known to

the applicant. A manufacturer must also report post-approval problems in labeling, manufacturing, and incidents where a device may have caused death or injury. The Court held that if liability arose as a result of failing to meet those requirements, Plaintiff's claims were not preempted. However, Plaintiff's Complaint failed to adequately plead this theory. Plaintiff's implied warranty, strict liability, and negligence claims were therefore dismissed.¹

- D. McCutcheon v. Zimmer Holdings, Inc., No. 06 C 6256, 2008 WL 3153442 (N.D. Ill. Aug. 6, 2008).** Defendant Zimmer Holdings manufactured N-K II, an artificial knee replacement classified as a Class III medical device by the FDA which received approval through the PMA process. Two years after installation, Plaintiff claimed the N-K II was defectively designed and manufactured using materials prone to wear, and that Zimmer was liable under theories of negligence, strict liability, and breach of warranties all under Illinois law. Zimmer argued Plaintiff's claims were preempted.

The Court concluded the Illinois tort principles upon which Plaintiff relied qualified as "requirements."

The Court rejected Plaintiff's contention that Zimmer failed to disclose accurate information to the FDA in the PMA process, principally because Plaintiff failed to produce evidence proving that fact. In any event, even if Zimmer committed a fraud on the FDA, the MDA impliedly preempted state law claims premised on a fraud perpetrated on the FDA pursuant to Buckman.

The Court also dismissed Plaintiff's contention that Reigel did not apply because the alleged defects were not discovered until after the FDA had completed the PMA process. Plaintiff relied on a footnote in the Riegel dissent indicating that the Court did not address the preemptive effect of section 360k(a) where evidence of a defect came to light after conclusion of the PMA process. Unfortunately, Plaintiff generated no proof of when knowledge of the defect became known.

- E. Clark v. Medtronic, Inc., — F. Supp. 2d —, 2008 WL 3851538 (D. Minn. Aug. 18, 2008).** Medtronic, Inc., manufactured a Model 7278 Maximo Implantable Cardioverter Defibrillator (ICD), a Class III medical device which had obtained PMA. The ICD was implanted in Plaintiff. Plaintiff thereafter returned to the hospital complaining of shocks. Plaintiff was eventually fitted with an ICD manufactured by a different company.

¹ Plaintiff's negligence per se and breach of express warranty claims failed for other reasons not relevant to this discussion.

Plaintiff sued Medtronic alleging various state tort claims, including strict liability, breach of warranty, negligence, misrepresentation, and violation of Minnesota's consumer protection laws. Plaintiff contended Medtronic was negligent in the design and manufacture of the ICD and/or had failed to warn him of the unreasonable risks in its manufacture or reliability. Medtronic claimed section 360k(a), as applied in Riegel, preempted Plaintiff's claims .

The Court agreed with Medtronic. The Court rejected Plaintiff's argument that Medtronic violated the PMA by manufacturing a defective product, and, alternatively, that Medtronic had fraudulently obtained PMA by concealing known defects in the ICD's design or manufacture. This argument failed because Plaintiff had no factual support to buttress it. Plaintiff's alternative res ipsa loquitur argument failed because there were a variety of reasons an ICD might fail, many of which were not dependent on the device being defectively designed or manufactured.

The Court also refused to agree that some of Plaintiff's claims were "narrower" than federal requirements because Plaintiff failed to demonstrate how his claims were narrower.

F. Kavalir v. Medtronic, Inc., No. 07-cv-0835, 2008 WL 4087950 (N.D. Ill. Aug. 27, 2008). Medtronic, Inc. manufactured an Implantable Cardioverter Defibrillator Device (ICD) that was implanted in Plaintiff in 2000. In 2003, Plaintiff experienced electrical shocks. Plaintiff purchased a new ICD from Medtronic in 2003. She then experienced a series of shocks from the new ICD, which eventually failed. Plaintiff filed a lawsuit against, among others, Medtronic, alleging strict liability and breach of warranty claims arising from defects in the 2000 and 2003 ICDs.

Among other things, Medtronic argued Plaintiff's state law claims were barred because the ICDs had been approved by the FDA under its PMA program. Medtronic asserted that Plaintiff's claims rested on the "common thread" that the ICDs sold by Medtronic were unsafe, unmerchantable, and unfit for their intended use. Medtronic attached to its motion printouts of pages from the FDA's webpage purportedly showing the two ICDs obtained FDA approval.

The Court held that printouts from the FDA's webpage were insufficient to determine what form or forms of the ICD received PMA and whether the ICDs that obtained PMA were the same model that were implanted in Plaintiff. As a result, the Court determined Plaintiff's claims were not preempted.

VI. Levine v. Wyeth, 944 A.2d 179 (Vt. 2006), cert. granted 128 S. Ct. 1118 (2008) (No. 06-1249).

- A.** Plaintiff was injected with Phenergan, a Wyeth product, to treat nausea resulting from a migraine headache. The drug was first administered by intramuscular injection. Later the same day, Plaintiff was injected a second time by direct IV injection. The second injection was inadvertently administered into an artery, which led to a gangrene infection and weeks of deterioration. Eventually, Plaintiff's hand and forearm were amputated.
- B.** Plaintiff brought two claims against Wyeth: (1) negligence, and (2) a claim alleging Wyeth had inadequately warned against the known dangers of direct IV injection. Plaintiff's experts contended the drug's label should not have allowed IV push as a method of administration and that it was safer to use alternative methods (e.g., intramuscular injection or hanging IV bag). Wyeth's expert testified that allowing an IV push with instructions cautioning against inadvertent arterial injection was sufficient. The trial court instructed the jury that it could consider the FDA's approval of the label, but that fact alone did not establish the adequacy of the warning, nor did it prevent Wyeth from adding to the label. The jury found in favor of the Plaintiff.
- C.** The Supreme Court of Vermont reviewed, among other things, Wyeth's contention that federal law preempted the Plaintiff's warning defect claims. This argument rested, in part, on Wyeth's claim that it had previously submitted a stronger warning to the FDA, but the FDA rejected it purportedly because the FDA did not favor the stronger warning. The trial court ruled that while the FDA had rejected the new warning, the agency failed to explain its reasoning or indicate it gave more than passing attention to the issue of how to safely administer the drug.
- D.** Wyeth argued a state common law duty to provide a stronger warning about the dangers of administering Phenergan by IV push conflicted with the FDA's approval of the drug's label. The Court ruled that the verdict against Wyeth did not conflict with the FDA's labeling requirements because Wyeth could have warned against IV-push administration without FDA approval and because federal labeling requirements create a floor—not a ceiling—for state regulation.

 - 1.** Wyeth presented a two-pronged approach: (1) with respect to the Phenergan label, the FDA was aware of the dangers of IV-push administration and specifically ordered Wyeth to use the warnings it used, making it impossible for Wyeth to comply with both its state common law duty and the requirements of federal law, and (2) by

penalizing drug companies for using FDA-approved wording on drug labels, state tort claims present an obstacle to the purpose of the FDA's labeling regulations.

2. The Court noted that 21 C.F.R. § 314.70(c) created a procedure allowing drug manufacturers to change labels that are insufficient to protect consumers despite the fact that the label had been approved by the FDA. The FDA-approved label thus created a minimum labeling requirement. As a result, section 314.70(c) allowed manufacturers to avoid state law failure-to-warn claims without violating federal law. According to the Court, state tort claims simply gave manufacturers an incentive to strengthen warnings sooner rather than later.

Importantly, the Court distinguished the case before it from MDA cases in which pre-Riegel courts had held that federal law preempted certain state law tort-based claims. The two cases cited by Wyeth were not persuasive: Buckman involved a “fraud-on-the-FDA” claim relating to device regulations which had nothing to do with the warning on the product; the Buckman Court specifically held that the presumption against preemption applies only where a claim implicates the historic primacy of state regulation of health and safety, which is not implicated when a claim arises from a federal statute but is the case when claims fall within the scope of traditionally state-regulated fields. Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004), involved an express preemption clause in the FDCA which related only to medical devices, which was absent in the case at bar.

3. With respect to the impossibility prong, Wyeth contended that it was impossible to comply with both federal and state regulations because, it argued, the FDA prohibited the use of a stronger warning with respect to IV-push administration of Phenergan. Rejecting this claim, the Court observed that that the record failed to show the FDA was concerning a stronger warning was (1) not supported by the facts, (2) a stronger warning would distract physicians from other provisions in the label, or (3) the warning might lead to less effective administration of the drug. Countering, Wyeth argued (1) the FDA approved the label that was used at the time of administration, and (2) when reviewing the label for a different version of Phenergan, the FDA expressed its opinion by stating: “Retain verbiage in current label.”

The Court held that the fact that the FDA had approved the label did not prevent a jury finding that the warnings contained in the label

were insufficient. This was so because section 317.70(c) permitted Wyeth to strengthen the language in the warning.

With respect to the FDA's review of the alternate label, the Court held that the FDA's language did not express the agency's intent that any strengthening of the original label would be prohibited. Wyeth argued that the FDA demonstrated that a stronger warning was both unnecessary and would have harmed patients by eliminating IV-push as a means of administering Phenergan. Dismissing this argument, the Court found no evidence suggesting the FDA arrived at an opinion regarding the value of IV-push administration. Rejecting the new label could have occurred for a variety of reasons, all of which could have had nothing to do with preserving the IV-push method of administration.

4. With respect to the obstacle prong, Wyeth argued imposing state common law liability operated as an obstacle to federal objectives. Opening with an analysis of the purposes and objectives of Congress, the Court reiterated that FDA regulations created a minimum standard, which was consistent with the FDCA's goal of protecting consumers. Moreover, the Court noted the Harris-Kefauver Act, which expressly limited the preemptive effect of amendments to the FDCA by eliminating the preemptive effect in the absence of a positive conflict.

The Court also considered the FDA's 2006 regulations which purportedly modified the preemptive effect of the FDCA. (The regulation itself was not applicable because it became effective after the harm suffered by Plaintiff.) The Plaintiff urged the Court to ignore the FDA's statements because they came into being without the requisite comment period.² The Court elected to pass on the issue, determining that the statement deserved no deference. This was so because Congress intended the FDCA to preempt only state laws that made it impossible for a defendant to comply with both federal and state obligations. Because manufacturers could enhance warnings without FDA approval, a manufacturer could comply with both

² Recalling, in United States v. Mead Corp., 533 U.S. 218, 226-27 (2001), the Supreme Court held that courts need only grant deference to agency regulations pursuant to Chevron U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1984) if "it appears Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." If the agency's interpretation is not entitled to Chevron deference, the regulation must be given "respect," but only "a respect proportional to its 'power to persuade.'" Id. at 235 (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

requirements, meaning there was no direct and positive conflict between state requirements and FDA regulations.

E. Dissenting, Chief Justice Reiber, concluded the jury's verdict was inconsistent with federal law for two reasons: (1) it would be impossible for Wyeth to comply with both the requirements of federal and state law and (2) plaintiff's state law claim posed an obstacle to federal purposes and objectives.

1. Regarding the impossibility prong, Justice Reiber concluded that the jury's verdict did something different than require a "stronger warning." Instead, the jury's verdict required the elimination of a use of Phenergan that the FDA had expressly approved. Justice Reiber further concluded that the FDA's rejection of Wyeth's attempt to change the language of the warning constituted affirmative evidence that the FDA preferred the language appearing in the warning.

First, Justice Reiber concluded that the verdict did not require a "stronger warning," but instead required the elimination of a method of administration. Justice Reiber analyzed Plaintiff's Complaint, wherein Plaintiff alleged Phenergan was not reasonably safe for IV administration. Justice Reiber also noted that Plaintiff's experts argued that the label should have restricted Phenergan to intramuscular injection, or, if IV was used, to a hanging IV bag. Plaintiff's argument was thus not that the warning was inadequate, but that an approved use was not reasonably safe.

Justice Reiber noted that the FDA addressed the risks associated with the direct IV injection method and warned of the dangers of IV administration, including inadvertent arterial injection. To Justice Reiber, this meant the FDA assessed the risks of IV administration, concluded the benefits of allowing such administration outweighed the risks, and determined what warning language adequately conveyed the risk.

Next, Justice Reiber concluded section 314.70(c) could not preserve Plaintiff's claims. Justice Reiber explained that section 314.70(c) allowed a manufacturer to strengthen a warning, but not eliminate an approved use. If Plaintiff prevailed, Justice Reiber explained, plaintiffs could impose upon manufacturers language that would contradict language expressly approved by the FDA.

However, even if section 314.70(c) allowed unilateral changes, Justice Reiber concluded that the FDA's rejection of attempts to change its warning regarding intra-arterial injection and amputation risks represented FDA approval of the warning as they appeared at the

time of use. The warning the FDA rejected highlighted the risk of gangrene and amputation if intra-arterial injection occurred. Justice Reiber concluded that the FDA approved all forms of IV administration, rendering the prohibition against some forms of IV administration sought by Plaintiff in conflict with that approval.

2. Regarding the obstacle prong, Justice Reiber concluded that the majority's reliance on the Harris-Kefauver Act to eliminate one of the two methods of proving conflict preemption was improper because no published opinion supported the decision that requiring a "direct and positive conflict" eliminated the "obstacle" method of proving preemption. Applying the standard test to determining whether enforcing the jury verdict would erect an obstacle to the purposes and objectives of the FDA's regulations, Justice Reiber observed the FDA was principally interested in public safety and was required to balance the need for safe pharmaceuticals against the risks inherent in any drug by approving the label affixed to the drug. To Justice Reiber, the jury's verdict conflicted with the FDA's assessment that Phenergan was safe and effective when delivered through IV administration.

VIII. Post Certiorari-Grant Cases.

- A. **Tofanelli v. Biogen Idec, Inc., No. 07-11840-DPW, 2008 WL 3824775 (D. Mass. Aug. 5, 2008).** Plaintiff filed a wrongful death action against three Defendants alleging a common failure to provide adequate warnings of the risks associated with the drug Tysabri, which had been approved by the FDA. Shortly after the Plaintiff's husband was infused with Tysabri, Defendants disclosed information regarding side effects of the drug by notifying the FDA that a patient participating in a clinical trial died from an opportunistic infection. Shortly thereafter, Tysabri was pulled from the market. Following the injury sustained by Plaintiff (her husband's death), Defendants obtained FDA approval to reintroduce Tysabri into the United States. The FDA approved the reintroduction, but with a label that included new warnings about the risks of atypical and opportunistic infections.

Plaintiff alleged that when Tysabri was initially marketed, Defendants possessed data indicating the use of Tysabri was associated with certain opportunistic and atypical infections. Plaintiff claimed that even though Defendants had this knowledge, the labeling lacked warnings concerning these effects.

Granting a motion to remand, the Court refused to hold that Defendants' argument that Plaintiffs' state law tort claims infringed on the FDA's drug

approval process and were therefore preempted gave rise to a defense with a federal ingredient.

IX. Concluding Thoughts.

A. How to Determine if a Claim is Preempted Under Riegel.

1. Does the claim relate to a medical device which received PMA?
2. Does a state requirement relate to the safety or effectiveness of the device or to any other matter included in a federal requirement? Does the claim rest on a violation of an FDA regulation?
3. Is there a federal requirement applicable to the device?
4. Does the state rule impose requirements “different from, or in addition to” the federal regulation? Does the state rule impose requirements “parallel” with the federal rule?

B. Assuming Wyeth is Reversed, How to Determine if A Claim is Preempted.

1. Is the claim related to a defect in a label previously approved by the FDA? (Does the claim require something in a label the FDA rejected?)
2. Does the claim impose a duty upon the manufacturer in excess of the approved label?
3. Does the claim require the elimination of an approved use?